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**United States Patent** [19]  
**Fortier**

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[54] **TROCAR WITH REMOVABLE,  
REPLACEABLE TIP**

[75] **Inventor:** **Richard C. Fortier, Concord, Mass.**

[73] **Assignee:** **NeoSurg Technologies, Houston, Tex.**

[\*] **Notice:** This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

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[51] **Int. Cl.<sup>7</sup>** **A61B 17/34**

[52] **U.S. Cl.** **606/185; 604/164.06**

[58] **Field of Search** **606/185; 604/164,  
604/164.01, 164.06; 30/340, 329; 81/489;  
16/422, 426, 427**

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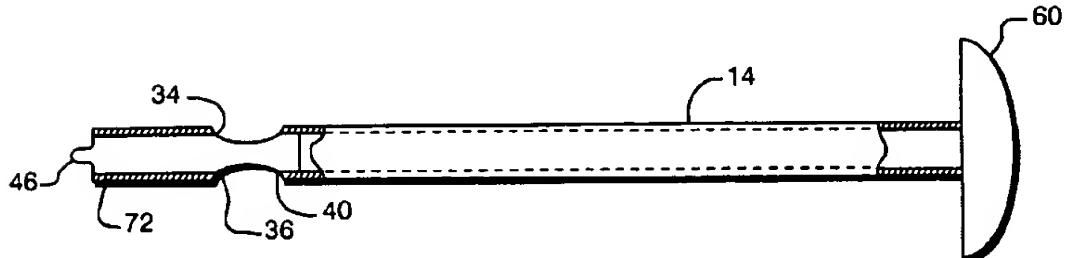
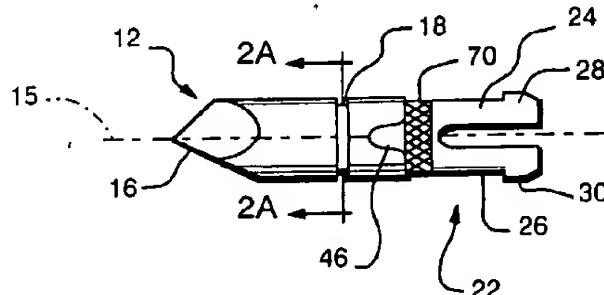
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*Primary Examiner*—Michael H. Thaler  
*Attorney, Agent, or Firm*—Iandiorio & Teska

[57] **ABSTRACT**

A trocar obturator having a removable replaceable tip includes an obturator tip having a sharpened distal end and a first engagement device on its proximal end; an obturator shaft having a second engagement device on its distal end for lockingly engaging the first engagement device and securing the tip and shaft together; one of the engagement devices borne by one of the tips and shafts includes a flexible member biased to engage the engagement devices; there are access means for flexing the flexible member against its bias to disengage the engagement devices to release the tip and shaft.

**28 Claims, 7 Drawing Sheets**



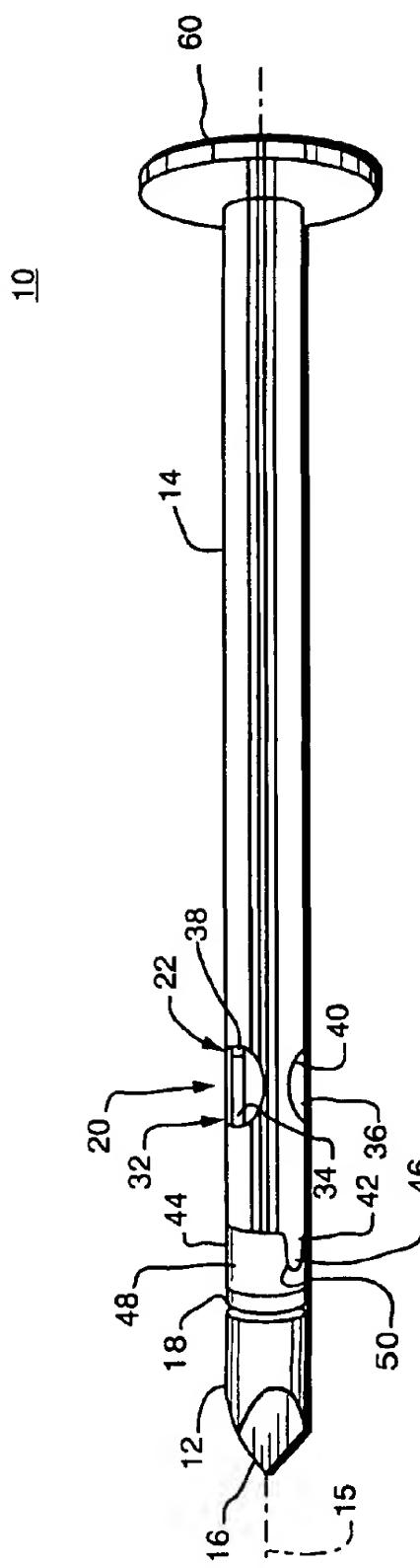
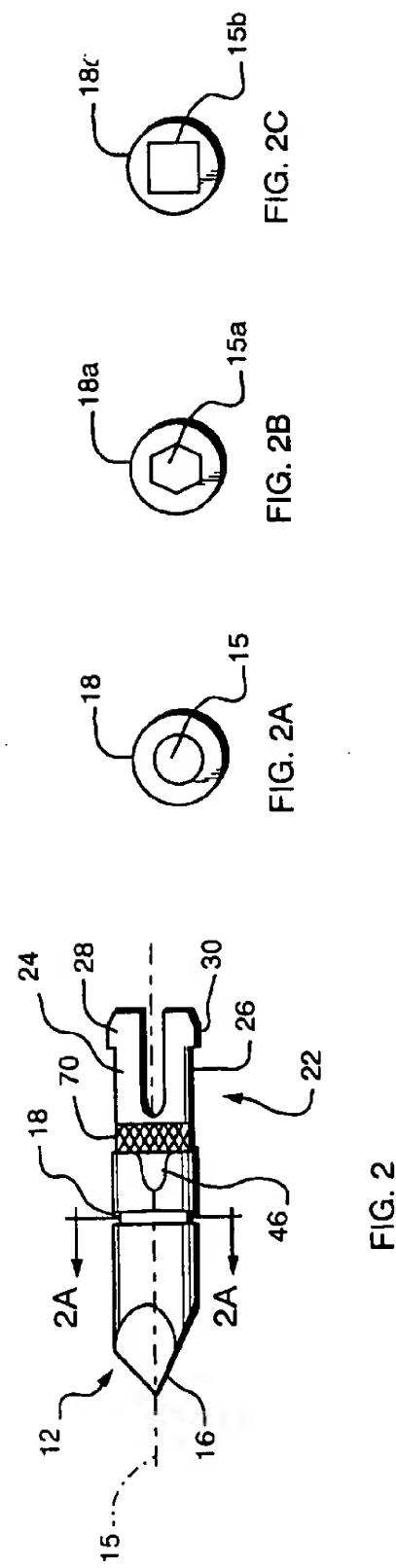
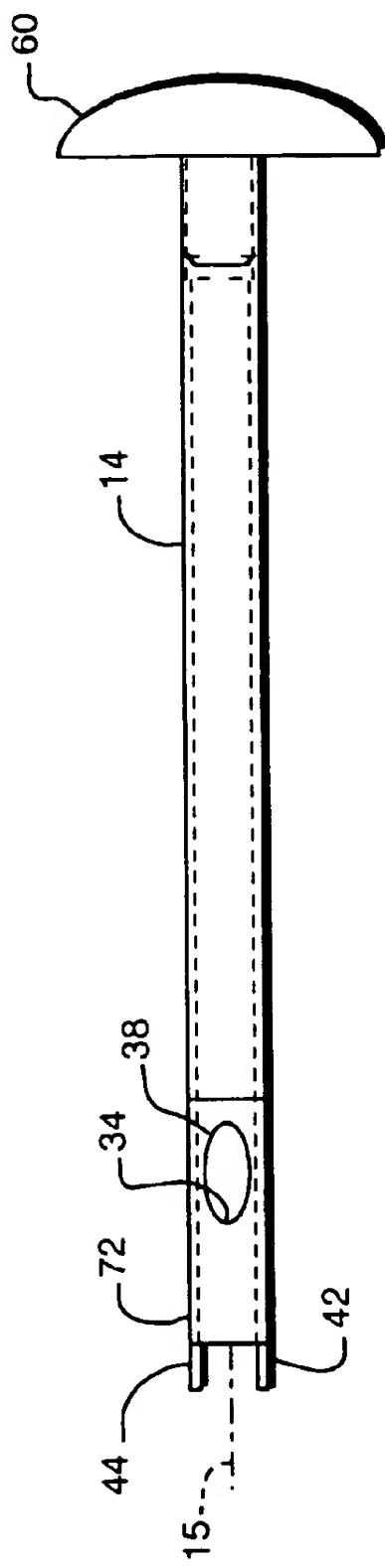


FIG. 1





3  
E  
G

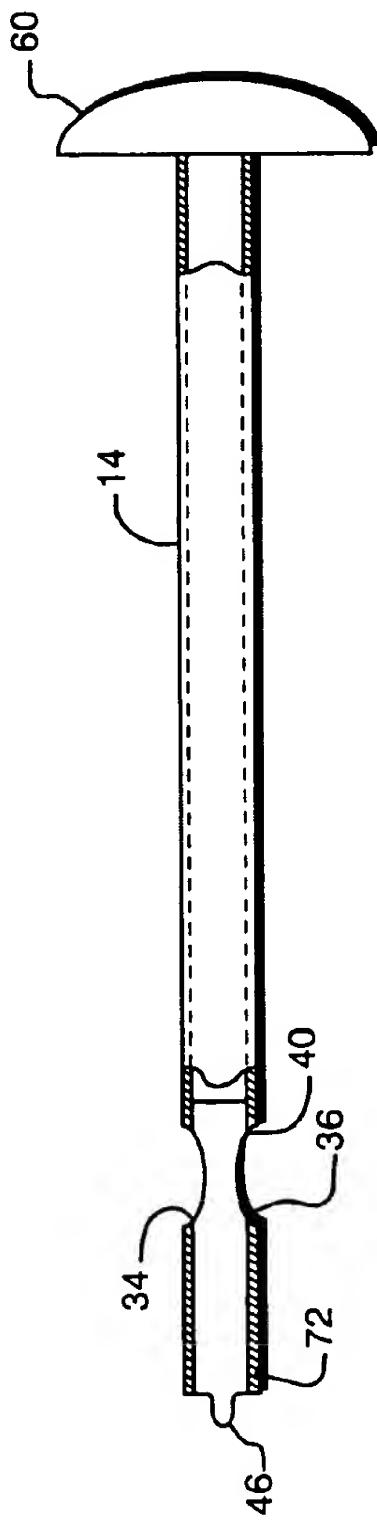
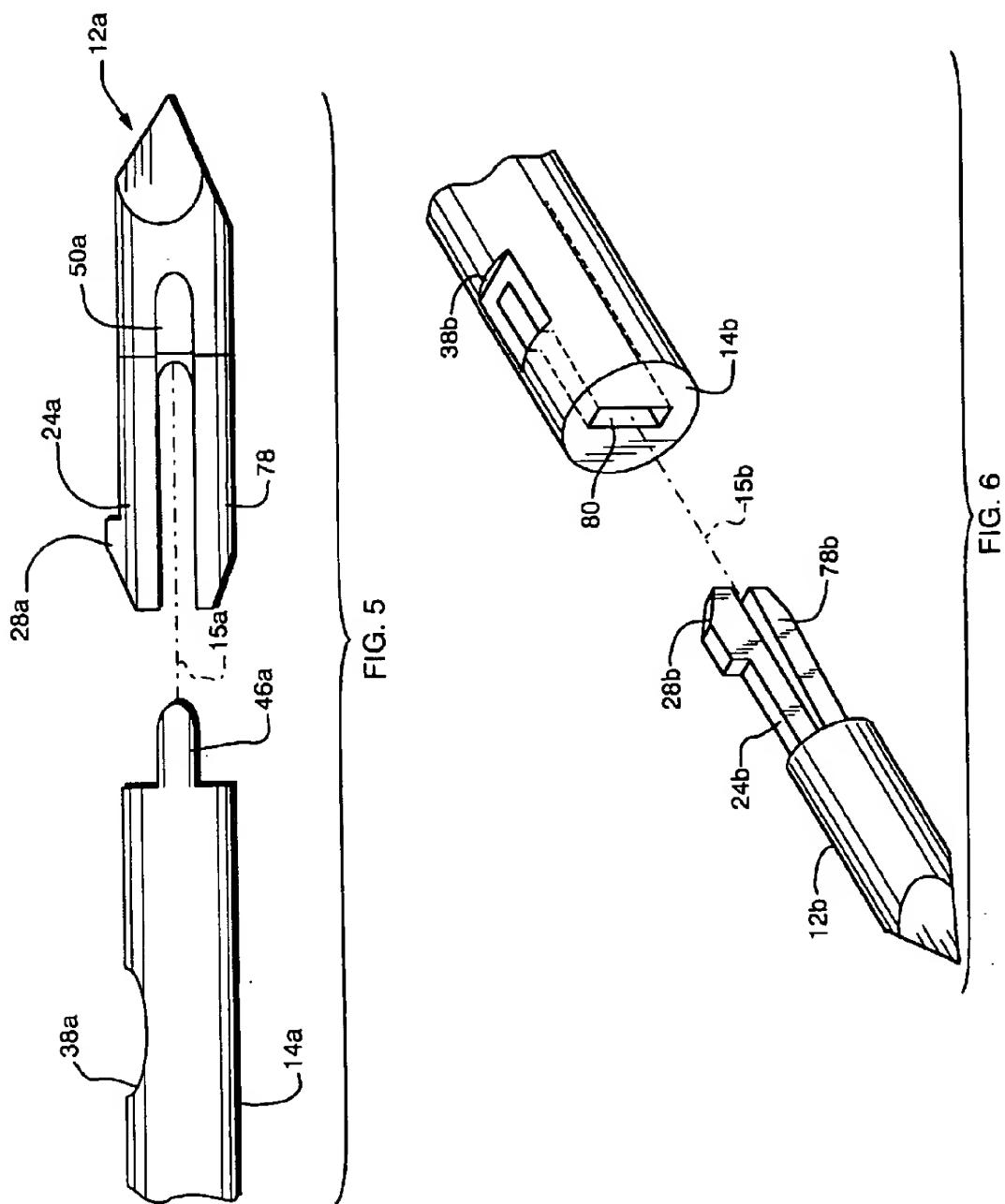


FIG. 4



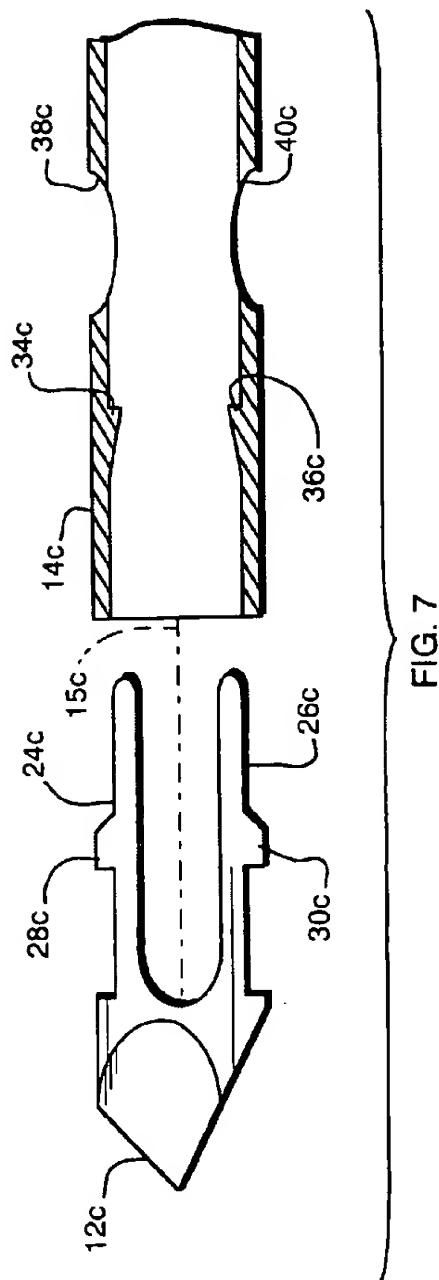


FIG. 7

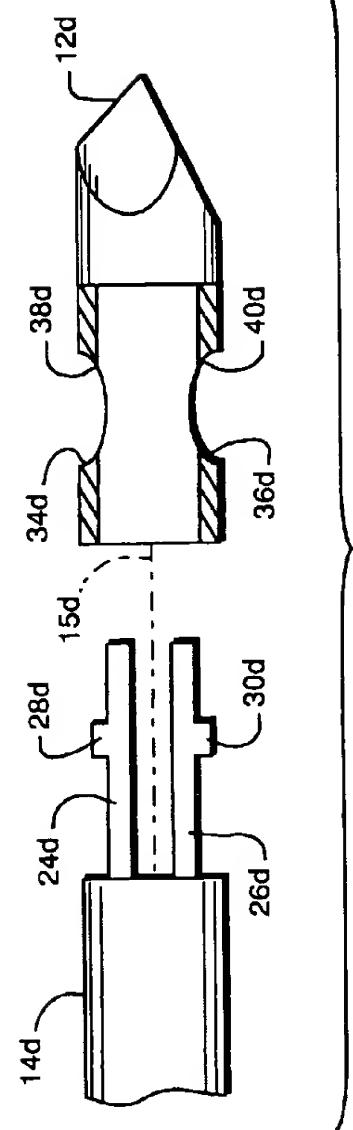


FIG. 8

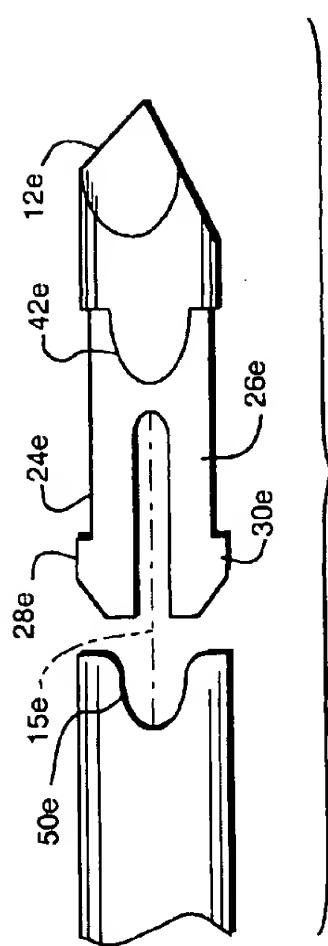


FIG. 9

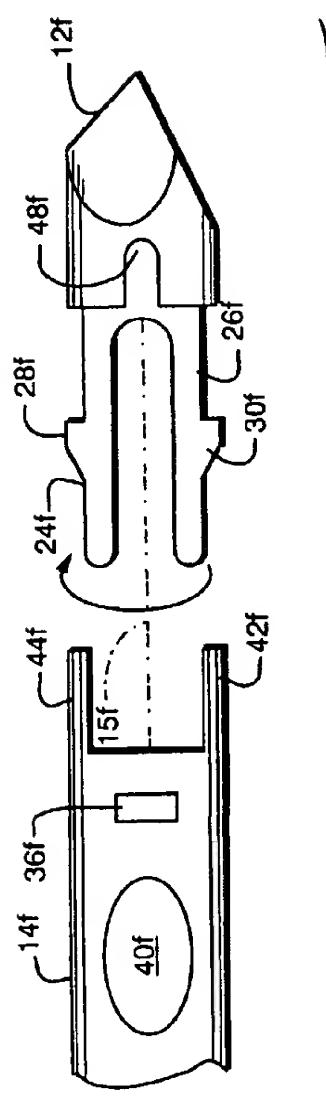
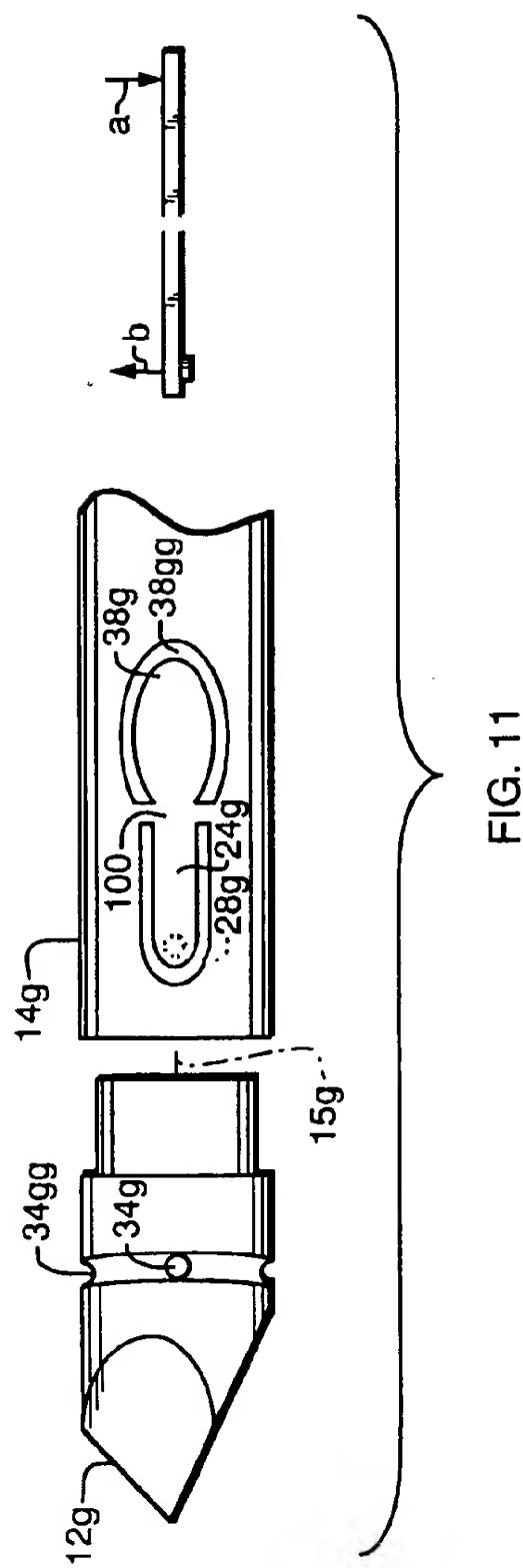


FIG. 10



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**TROCAR WITH REMOVABLE,  
REPLACEABLE TIP**

**FIELD OF INVENTION**

This invention relates to an improved obturator having a removable, replaceable tip and more particularly to such a removable, replaceable tip which flexibly engages and releases the obturator tip and shaft.

**BACKGROUND OF INVENTION**

Conventional trocars use an obturator with a sharp metal tip to penetrate a body cavity in surgical procedures. After each use the obturator must be sterilized and eventually the tip dulls and must be re-sharpened by machining. These obturators are expensive and adding to their effective cost is the cost of sharpening, sterilizing and the loss of use during those procedures. Some trocars including housing, handle, cannula and obturator are made to be disposable: they are made to be used once and discarded with no need for resharpening or sterilizing but their initial cost is quite high. Some trocar obturators are made with a removable metal tip so that tips of different cutting configurations can be used by simple removal and replacement of them from the obturator shaft. But these tips, too, are expensive and must be regularly sterilized and periodically re-sharpened.

**SUMMARY OF INVENTION: I**

It is therefore an object of this invention to provide an improved obturator having a removable, replaceable tip.

It is a further object of this invention to provide such an obturator which is disposable after a single use.

It is a further object of this invention to provide such an obturator which is inexpensive and easy to install and removal.

It is a further object of this invention to provide such an obturator which is always at peak sharpness and sterile and involves no re-sharpening or sterilization.

It is a further object of this invention to provide such an obturator which sensibly indicates when the tip is seated in the shaft.

The invention results from the realization that a truly cost effective, disposable obturator can be achieved with a separable tip and shaft which have means for properly orienting them and releasably engaging and disengaging them using a flexible member on one bearing a detent which engages with a stop on the other under the bias of the flexible member to secure the tip and shaft which can easily be disengaged by moving the flexible member against its bias to release the detent from the stop and free the tip from the shaft.

This invention features a trocar obturator having a removable replaceable tip including an obturator tip having a sharpened distal end and a first engagement device on its proximal end. There is an obturator shaft having a second engagement device on its distal end for lockingly engaging the first engagement device and securing the tip and shaft together. One of the engagement devices borne by one of the tips and shafts includes a flexible member biased to engage the engagement devices. There are access means for flexing the flexible member against its bias to disengage the engagement devices to release the tip and shaft.

In a preferred embodiment there may be alignment means for defining orientation of the tip and shaft. The alignment means may include a salient portion on one of the tip and shaft and a mating recess on the other. One of the engage-

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ment devices on one of the tips and shafts may be asymmetrical in shape and the alignment means may include a conforming guide recess on the other of the tip and shaft for orienting the tip and shaft. The tip may include a circumferential removal groove. The groove may have a circular shape or a polygonal shape such as a square. There may be an indicator surface on one of the tips and shafts and a cover member on the other for covering the indicator surface when the tip and shaft are engaged. The indicator surface may include a contrasting color region. The flexible member may snap the engagement devices together to make an audible indication that the tip and shaft are secured. The tip may be made of plastic such as polycarbonate, ABS, or polysulfone. One of the engagement devices may include at least one flexible leg with a detent and the other engagement device may include a stop means for engaging the detent. The flexible leg may be included on the first engagement device on the tip and the stop means may be on the second engagement device on the shaft. Or the flexible leg may be on the second engagement device on the shaft and the stop means may be on the first engagement device on the tip. The stop means may include a stop recess for receiving the detent or it may include a stop shoulder for abutting the detent. The access means may include a port for manipulating the flexible leg and it may be on the shaft or the tip. The access means may include a resilient tab interconnected with the flexible leg for flexing the leg against its bias to release the tip and shaft. The stop means may include a peripheral slot.

The invention also features a trocar obturator having a removable replaceable tip including an obturator tip having a sharpened distal end and a flexible leg extending from the proximal end and having a detent thereon. An obturator shaft has a stop means for engaging the detent. The flexible leg is biased to engage the detent and stop means to secure the tip and shaft. An access port is provided for moving the leg to overcome its bias, disengage the detent and stop means and release the tip and shaft.

In a preferred embodiment the stop means may include a stop recess for receiving the detent or a stop shoulder for abutting the detent. The access port may be in the shaft and the stop recess may form a part of the port.

This invention also features a trocar obturator having a removable replaceable tip including an obturator tip having a sharpened distal end, an obturator shaft, and engaging means for releasably securing the tip and shaft including a flexible leg having a detent on one of the tip and shaft and stop means on the other for engaging the detent, the flexible leg being biased to engage the detent and stop means and secure the tip and shaft. There are access means for moving the leg to overcome its bias, disengage the detent and stop means and release the tip and shaft.

In a preferred embodiment the flexible leg may be on the tip and the stop means may be on the shaft, or the flexible leg may be on the shaft and the stop means on the tip.

**DISCLOSURE OF PREFERRED EMBODIMENT**

Other objects, features and advantages will occur to those skilled in the art from the following description of a preferred embodiment and the accompanying drawings, in which:

FIG. 1 is a three-dimensional view of a trocar obturator including a removable replaceable tip according to this invention;

FIG. 2 is an enlarged detail view of the obturator tip of FIG. 1;

FIG. 2A is a cross-sectional view taken along lines 2A-2A of FIG. 2 showing a groove which has a circular shape;

FIG. 2B is a view similar to FIG. 2A in which the groove has a polygonal shape;

FIG. 2C is a view similar to FIGS. 2A and 2B wherein the groove has a square shape;

FIG. 3 is an enlarged detailed plan view of the obturator shaft of FIG. 1;

FIG. 4 is an enlarged detailed elevational view of the obturator shaft of FIG. 1;

FIG. 5 is a view similar to FIG. 2 wherein there is but one flexible leg, one detent and one access hole;

FIG. 6 is a three-dimensional view of the tip of FIG. 5 showing an asymmetric slot in the shaft for definitively orienting the tip and shaft assembly;

FIG. 7 is an enlarged detailed side elevational view of another embodiment of the removable replaceable tip according to this invention employing two flexible legs with detents for mating with internal stop shoulders on the shaft;

FIG. 8 is a view similar to FIG. 7 of another embodiment of the removable replaceable tip according to this invention in which flexible legs with detents are on the shaft and the tip contains access ports a portion of which function as stop recesses;

FIG. 9 is a view similar to FIG. 2 in which the alignment means have the salient portion on the tip and the mating recess portion on the shaft;

FIG. 10 is a view similar to FIG. 9 of another embodiment of the removable replaceable tip of this invention in which the stop means includes a stop recess separate from the access port; and

FIG. 11 is a view similar to FIG. 9 of another embodiment of the removable replaceable tip of this invention in which the detent is borne by a flexible leg interconnected with a resilient actuator tab on the shaft and the stop recess is a circumferential groove on the tip.

There is shown in FIG. 1 a trocar obturator 10 according to this invention including an obturator tip 12 and shaft 14 with a longitudinal axis 15. Tip 12 includes a sharpened distal end 16 and a removal groove 18 for receiving, for example, forceps, to remove tip 12 from shaft 14. Referring to FIGS. 1, 2, 3 and 4, it can be seen that there are engagement means 20 which include an engagement device 22 on tip 12 comprised of a pair of flexible legs 24, 26 having detents 28 and 30. There is also an engagement device 32 on shaft 14 which includes the stop means formed by the stop recesses 34 and 36 that form a part of the oval ports 38 and 40 that constitute the access means by which the fingers of a surgeon can reach and squeeze legs 24 and 26 to move detents 28 and 30 out of contact with stop recesses 34 and 36 in order to release tip 12 from shaft 14. Flexible legs 24 and 26 have a sufficient bias to maintain detents 28 and 30 in contact with stop recesses 34 and 36 and to provide a snap fit which makes a clicking noise when tip 12 is inserted and seated properly in shaft 14 so the surgeon has an audible confirmation that the shaft and tip are locked together. In order to compel the tip 12 to be inserted in shaft 14 so that legs 24 and 26 align with access ports 38 and 40, alignment means 42 consisting of tabs 44 and 46 extending saliently from shaft 14 and recesses 48 and 50 on tip 12 are provided. A handle or hub 60 is provided on the proximal end of shaft 14 to be used to apply pressure to push the sharp end 16 of tip 12 through the body tissue. Shaft 14 is hollow, at least at its distal end to provide for access ports 38 and 40 and permit the legs 24 and 26 of tip 12 to be inserted. To provide for strength, sharp cutting edges and the snap fitting action and sound, the trocar may be made of a metal or of a plastic such as of polycarbonate, ABS, polysulfone.

Visual indicia may be provided in the form of a contrasting color or texture or pattern 70, FIG. 2, which will be covered by cover portion 72, FIGS. 3 and 4, of shaft 14 when tip 12 is properly secured in shaft 14 so the surgeon will have another confirmation that the obturator is properly and safely assembled.

In operation, tip 12 is inserted in shaft 14 by simply pressing the ends of legs 24 and 26 against the cover portion 72 of shaft 14. Legs 24 and 26, being flexible, will flex inward so that detents 28 and 30 will pass under the cover portion and will spring out in ports 38 and 40 making a clicking sound when detents 28 and 30 spring into position at stop recesses 34 and 36. At this point the color band 70 will no longer be visible as it is hidden by the cover portion 72. When the surgical procedure is finished and it is desired to remove tip 12, tip 12 can be gripped by fingers or by a tool such as a forcep which would engage with groove 18 and then the surgeon may place a thumb and forefinger over access ports 38 and 40, depressing legs 24 and 26 so that detents 28 and 30 disengage from stop recesses 34 and 36.

Groove 18 has a circular shape or circumference as shown in FIG. 2A, but it may as well have a polygonal shape such as hexagonal shape 18a, FIG. 2B, or square shape 18b, FIG. 2C, to better receive a wrench-like conformation or forceps.

Although in FIGS. 1-4 tip 12 is shown with a pair of flexible legs with detents and a pair of access ports, as well as a pair of alignment tabs these are not necessary limitations of the invention. For as shown in FIG. 5, tip 12a may include a single recess 44a to receive a single salient tab 46a. Obturator tip 12a has but a single flexible leg 24a with detent 28a accessible through a single port 38a. All tabs 46 and recesses 50a used for alignment purposes may be eliminated, for example, and replaced by an alignment slot 80, FIG. 6, which is asymmetrical and conformed to receive the asymmetrical shaped legs 24b and 78b so that the tip 12b is automatically properly aligned with shaft 14b. Element 78 which may take any particular form including a shape similar to leg 24a may be provided to keep tip 12a trued up and properly oriented in shaft 14a.

While the stop means thus far have been shown as a part of access ports 38 and 40, this is not a necessary limitation of the invention as they may in fact be constructed as internal stop shoulders 34c, 36c, FIG. 7, which engage detents 28c and 30c on legs 24c and 26c.

In addition, although thus far the flexible leg or legs and detents have been shown as a part of the tip and the access ports and stop means have been shown as a part of the shaft, this is not a necessary limitation of the invention as the converse is also contemplated by this invention as shown in FIG. 8, where tip 12d includes access ports 38d and 40d having stop recesses 34d and 36d while shaft 14d contains flexible legs 24d and 26d having detents 28d and 30d. In addition, although the alignment means have been shown with the salient tab on the shaft and the recess on the tip, this is not a necessary limitation of the invention, for as shown in FIG. 9 one or more salient tabs 42e may be provided on tip 12e to self-center and nest in one or more recesses 50e.

The access port or ports for reaching flexible legs and compressing them inwardly against their bias may not provide a recessed stop as a part of its configuration. Rather, as shown in FIG. 10, where tip 12f has been rotated 90° with respect to shaft 14f the stop recess 34, 36f has been independently provided to engage detent 28f on leg 24f and a similar stop recess, not shown, is provided on the opposite side of shaft 14f. In FIG. 10, for proper rotational orientation of the tip 12f and shaft 14f, tip 12f must be rotated so that

leg 24f comes out of the paper and leg 26f rotates into the paper about the central longitudinal axis 15 so that detent 24 fits into stop recess 36f.

Although the access means has been shown as one or more ports, this is not a necessary limitation of the invention. For example, as shown in FIG. 11, flexible leg 24g having internally extending detent 28g is flexibly interconnected at junction 100, FIG. 11, with access actuator tab 38g in opening 38gg so that a downward pressure on tab 38g rocks leg 24g upwardly, lifting detent 28g out of stop recess hole 34g. A similar construction may be duplicated on the opposite side of tip 12g and shaft 14g. Hole 34g may be replaced by a circumferential slot 34gg so that orientation is not a problem as detent 28g and a complementary one on the other side of shaft 14g can engage anywhere along groove 34gg.

Although specific features of this invention are shown in some drawings and not others, this is for convenience only as each feature may be combined with any or all of the other features in accordance with the invention.

Other embodiments will occur to those skilled in the art and are within the following claims:

What is claimed is:

1. An obturator having a removable replaceable tip comprising:
  - an obturator tip having a sharpened distal end and a first engagement device on its proximal end;
  - an easily sterilizable tubular, hollow-bodied obturator shaft having a second engagement device on its distal end for lockingly engaging said first engagement device and securing said tip and shaft together;
  - one of said engagement devices borne by one of said tip and shaft including a flexible member biased to engage the other said engagement device; and
  - toolless access means for enabling the use to directly access and flex, toward the radial center of said shaft, said flexible member against its bias to disengage said engagement devices to release said tip from said shaft, said toolless access means operatively sized and shaped to receive the user's finger such that the user can disengage said engagement devices without using any tools.
2. The obturator of claim 1 further including alignment means for defining orientation of said tip and shaft.
3. The obturator of claim 2 in which said alignment means includes a salient portion on one of said tips and shafts and a mating recess on the other.
4. The obturator of claim 2 in which one of said engagement devices on one of said tip and shaft is asymmetrical in shape and said alignment means includes a conforming guide recess on the other of said tip and shaft for orienting said tip and shaft.
5. The obturator of claim 1 in which said tip includes a circumferential removal groove.
6. The obturator of claim 5 in which said groove has a circular shape.
7. The obturator of claim 5 in which said groove has a polygonal shape.
8. The obturator of claim 1 further including an indicator surface on one of said tip and shaft and a cover member on the other for covering said indicator surface when said tip and shaft are engaged.
9. The obturator of claim 1 in which said indicator surface includes a contrasting colored region.
10. The obturator of claim 1 in which said flexible member snaps said engagement devices together to make an audible indication that said tip and shaft are secured.
11. The obturator of claim 1 in which said tip is made of plastic.

12. The obturator of claim 11 in which said plastic is from the group consisting of polycarbonate, ABS and polysulfone.

13. The obturator of claim 1 in which one of said engagement devices includes at least one flexible leg with a detent and the other engagement device includes a stop for engaging said detent.

14. The obturator of claim 13 in which said stop means is a stop recess for receiving said detent.

15. The obturator of claim 13 in which said stop means is a stop shoulder for abutting said detent.

16. The obturator of claim 13 in which said access means includes a port which allows for manual manipulation of said flexible leg.

17. The obturator of claim 13 in which said stop means includes a peripheral slot.

18. The obturator of claim 1 in which said flexible leg is included on said first engagement device on said tip and said stop means is on said second engagement device on said shaft.

19. The obturator of claim 1 in which said flexible leg is included on said second engagement device on said shaft and said stop means is on said first engagement device on said tip.

20. The obturator of claim 1 in which said access means is on said shaft.

21. The obturator of claim 1 in which said access means is on said tip.

22. An obturator having a removable, replaceable tip comprising:

- an obturator tip having a sharpened distal end and a flexible leg extending from the proximal end and having a detent thereon;
- an tubular, hollow bodied obturator shaft having stop means for engagement with said detent, said flexible leg being biased to engage said detent with said stop means to secure said tip and shaft; and
- a toolless access port to enable the user to directly access and flex said leg inward toward the radial center of said shaft to overcome its bias, disengage said detent and stop means and release said tip from said shaft.

23. The obturator of claim 22 in which said stop means includes a stop recess for receiving said detent.

24. The obturator of claim 22 in which said stop means includes a stop shoulder for abutting said detent.

25. The obturator of claim 22 in which said access port is in said shaft and said stop recess forms a part of said port.

26. An obturator having a removable, replaceable tip comprising:

- an obturator tip having a sharpened distal end;
- an tubular, hollow bodied obturator shaft
- engaging means for releasably securing said tip and shaft including a flexible leg having a detent on one of said tip and shaft and stop means on the other for engagement with said detent; said flexible leg being biased to engage said detent with said stop means and secure said tip and shaft; and
- access means for enabling the user to directly access and move said leg inward toward the radial center of said shaft to overcome its bias, disengage said detent and stop means and release said tip from said shaft.

27. The obturator of claim 26 in which said flexible leg is on said tip and said stop means is on said shaft.

28. The obturator of claim 26 in which said flexible leg is on said shaft and said stop means is on said tip.

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**United States Patent** [19]

Stephens

[11] Patent Number: **5,690,663**[45] Date of Patent: **Nov. 25, 1997**[54] **SAFETY TROCAR**[75] Inventor: **Randy R. Stephens, Fairfield, Ohio**[73] Assignee: **Ethicon Endo-Surgery Inc., Cincinnati, Ohio**[21] Appl. No.: **657,532**[22] Filed: **Jun. 4, 1996****Related U.S. Application Data**

[63] Continuation of Ser. No. 296,217, Aug. 25, 1994, abandoned.

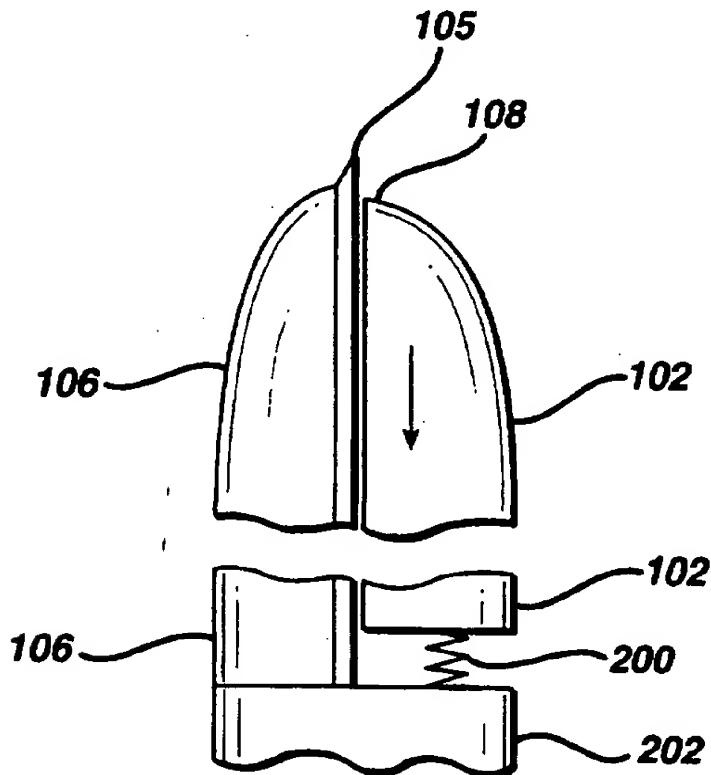
[51] Int. Cl<sup>6</sup> **A61B 17/34**[52] U.S. Cl. **606/185; 604/264**[58] Field of Search **604/164, 264; 606/1, 167, 171-185**[56] **References Cited****U.S. PATENT DOCUMENTS**5,263,937 11/1993 Shipp **604/264**

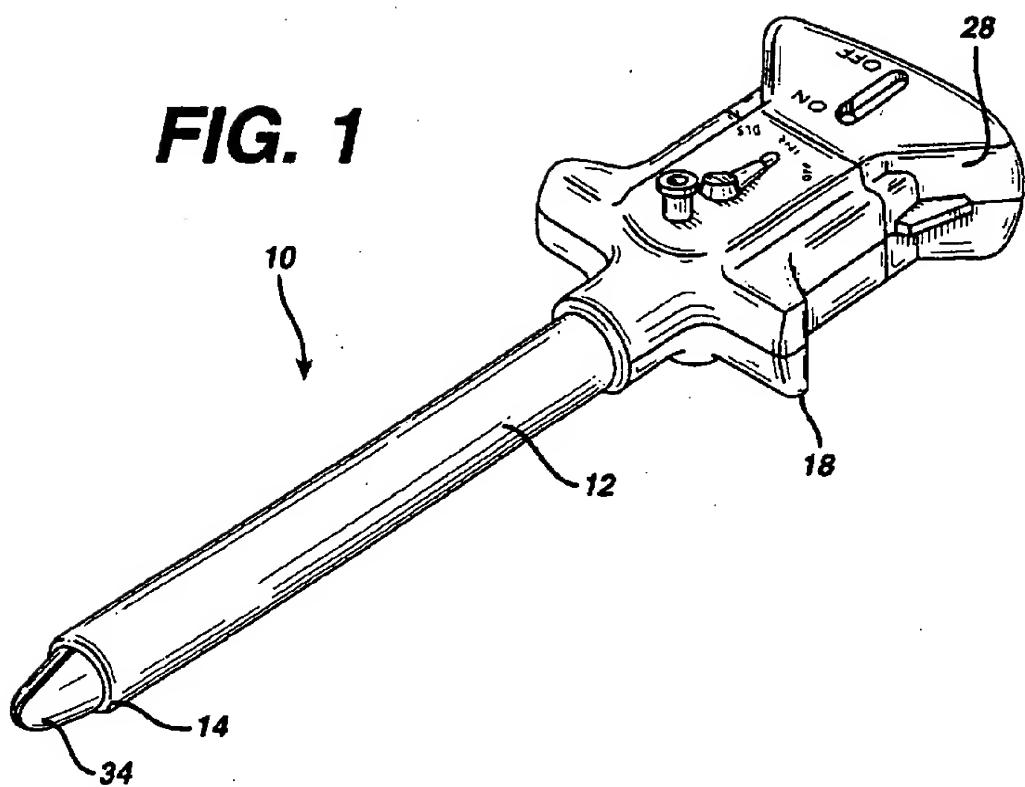
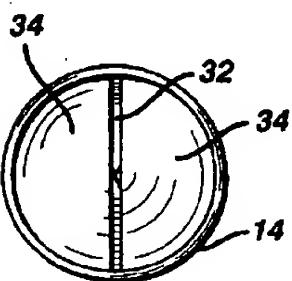
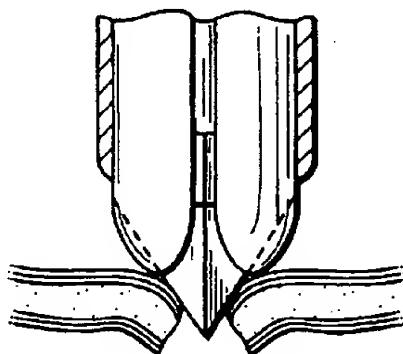
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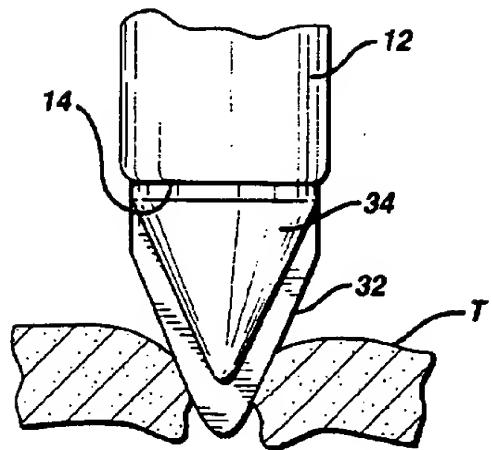
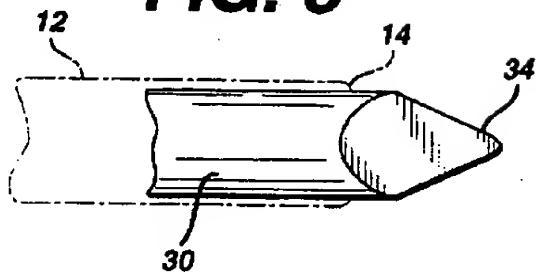
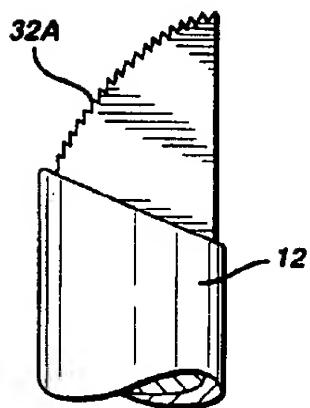
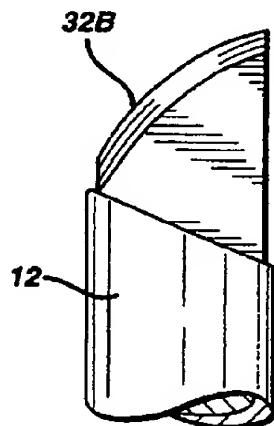
*Primary Examiner*—Glenn Dawson  
*Attorney, Agent, or Firm*—Paul A. Coletti

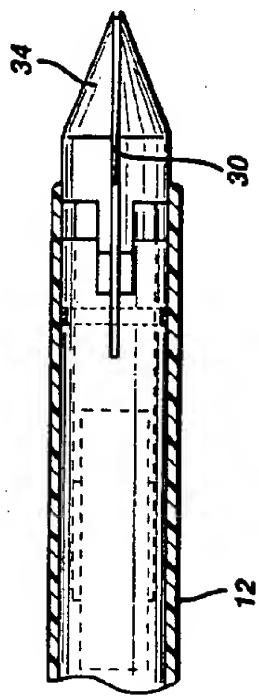
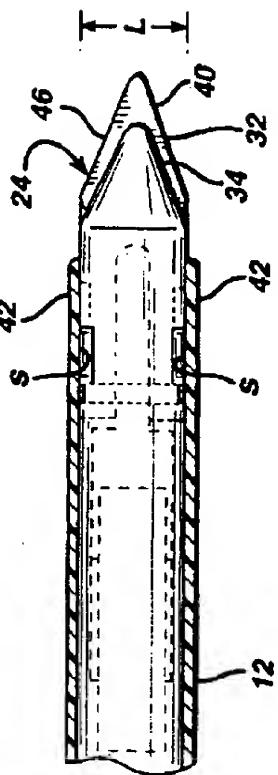
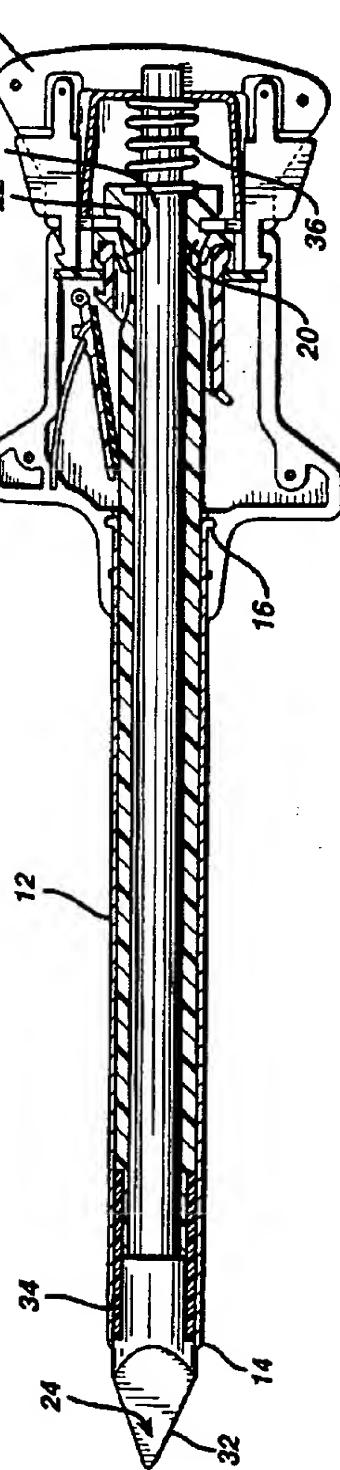
[57] **ABSTRACT**

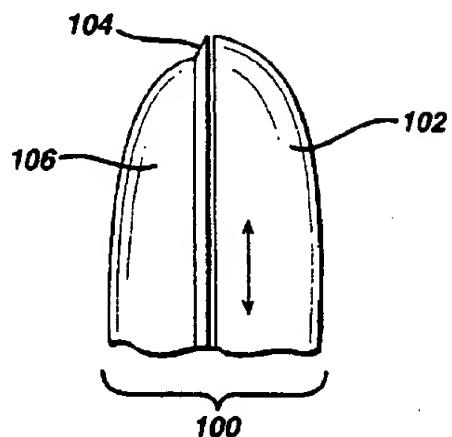
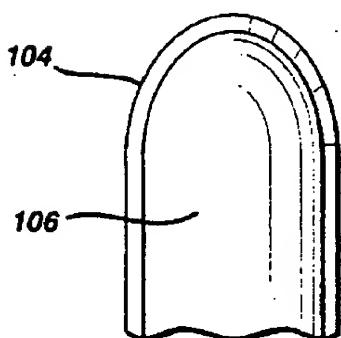
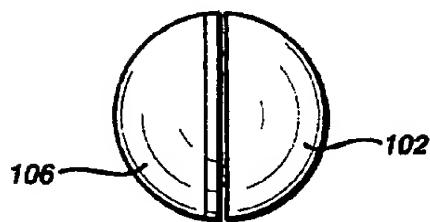
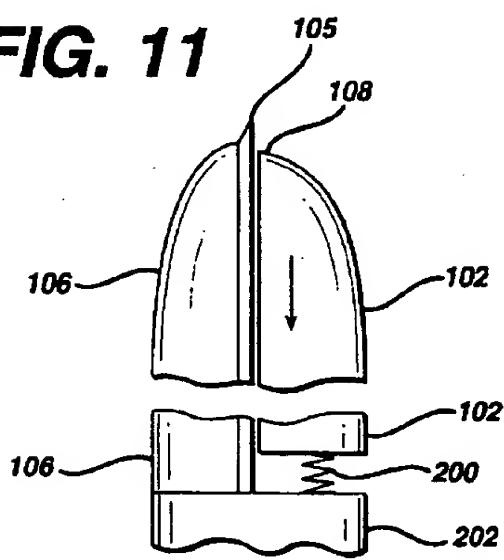
A safety trocar is provided which includes a spring-loaded shield that shields the cutting tip of the obturator after the obturator penetrates tissue. The distal end of the shield is conical in profile and contains a slot which conforms to the geometry of the cutting tip. The obturator tip contains a knife edge blade which extends the length of the cannula inner diameter. Ideally, the knife is made of an amorphous metal, and may be serrated at its edge. In one embodiment, the knife edge is contacted directly to a portion of the safety shield.

**4 Claims, 4 Drawing Sheets**

**FIG. 1****FIG. 2****FIG. 3**PRIOR ART

**FIG. 4****FIG. 5****FIG. 6a****FIG. 6b**

**FIG. 7a****FIG. 7b****FIG. 8**

**FIG. 9****FIG. 9A****FIG. 10****FIG. 11**

## SAFETY TROCAR

This is a continuation of application Ser. No. 08/296,217, filed Aug. 25, 1994 now abandoned.

## FIELD OF THE INVENTION

This invention relates to trocars used to puncture tissue for the performance of laparoscopic or arthroscopic surgery and, in particular, to such trocars which employ a safety device to shield the obturator point immediately after the point has perforated tissue.

## BACKGROUND OF THE INVENTION

A trocar generally comprises two major components, a trocar tube and an obturator. The trocar tube or cannula is inserted through the skin. Access is gained through to a body cavity so that laparoscopic or arthroscopic surgery may be performed. In order to penetrate the skin, the distal end of the trocar tube is placed against the skin and an obturator is inserted through the tube. By pressing against the proximal end of the obturator the point of the obturator is forced through the skin until the obturator enters the body cavity. At this time, the trocar tube is inserted through the perforation made by the obturator and the obturator is withdrawn, leaving the trocar tube as an accessway to the body cavity.

It has been found that often a great deal of force is required to cause the obturator point to penetrate the skin and underlying tissue. When the point finally breaks through this tissue, resistance to penetration is suddenly removed, and the obturator point can suddenly reach to penetrate internal organs of the body, which may cause lacerations and other injury to the internal organs. To avert this danger to the patient, trocars have been developed which carry a spring-loaded tubular shield within the trocar tube and surrounding the obturator. The distal end of the shield presses against the skin as the obturator point penetrates the body, until the obturator has formed a perforation with a diameter sufficient to allow the safety shield to pass through. At that time the resistance of the tissue to the spring-loaded shield is removed, and the shield will spring forward to extend into the body cavity, surrounding the point of the obturator. The shield thus protects the internal body organs from inadvertent contact with the point of the obturator. A trocar including such a safety shield is described in U.S. Pat. No. 4,535,773, for example.

The tubular shield in such a trocar will, however, require the incision formed by the obturator to extend to a considerable diameter before the resistance of the tissue pressure has been sufficiently decreased to allow the safety shield to spring forward. It is only when the incision attains the diameter of the shield that the shield is fully able to spring into the body cavity. When the obturator employs a long, tapered cutting tip, this tip must extend a significant distance into the body before the incision is sufficiently enlarged to release the safety shield. It would therefore be desirable to provide a safety shield which will spring forward to shield the obturator tip as soon as possible after entry is gained to the body cavity.

In accordance with the principles of Denlega, U.S. Pat. No. 5,066,288, a safety shield for a trocar obturator is provided which exhibits a rounded, bullet-shaped distal end. A slot is formed in this distal end which corresponds to the geometry of the obturator tip, through which the tip extends during perforation of the skin. With this distal end conforming to the geometry of the tip, a smooth transition is provided from the tip to the distal end of the shield, enabling the shield

to closely follow the obturator tip through the tissue. The rounded distal end will press against the skin and tissue in close proximity to the periphery of the incision as it is formed, and will aid in the enlargement of the incision to enable the shield to spring forward nearly as soon as entry is gained into the body cavity.

One desirable function of such a trocar is for the obturator to slide smoothly within the trocar tube during both insertion and retraction of the obturator. Opposing this need is the necessity to form the obturator to be nearly the same diameter as the tube, so that the tissue perforation will be the size of the tube. Thus, tolerances are generally tight between the diameter of the obturator and the inside diameter of the trocar tube. A further complication is provided by the valve 10 at the proximal end of the trocar tube, which is needed to seal the proximal end during removal of the obturator when the trocar tube and body cavity are insufflated with gases. The valve, which generally takes the form of a hinged flap or trumpet valve, is spring-loaded to bear against the obturator, thereby assuring that the valve will close automatically upon withdrawal of the obturator from the trocar tube. As the valve bears against the obturator it will frictionally disrupt the entry and withdrawal of the obturator. As 15 a result of these tolerance problems, heretofore there has not been an obturator which corresponds identically to the shaft of the trocar cannula, and wider than the inner dimension of the safety shield in which the obturator slides.

Further patient safety would be provided by preventing the sudden extension of the obturator into the body cavity as the obturator tip fully penetrates the tissue. In accordance with yet another aspect of Denlega '688, means are provided which permit only incremental advancement of the obturator as tissue penetration proceeds. Such incremental advancement is provided by a ratchet or screw mechanism, for instance. Yet, this has not alleviated the problem of having an obturator tip with only minimal exposure past the edge of the safety shield at all positions of the safety shield distal end.

## SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide a trocar with a safety shield such that the cutting edge of the obturator tip of the safety shield corresponds with the inner diameter of the trocar cannula. This improvement would reduce the force to penetrate the abdominal wall with using such trocar.

It is further desirable to form the obturator tip out of any one of the amorphous-type metals which have currently come into use. These amorphous metals such as amorphous steels and the like, have heretofore not been used in the medical industry for tissue piercing purposes, such as in trocar obturator tips.

Further, it is an object of the invention to provide a safety shielded trocar with a conical shape shield. This type of shield provides for ease of tissues spreading, and as well as adapts to be conformable to various types of obturator tips.

In this type of safety shield it is desired to provide a diametral slot. This slot allows passage of the knife edge which causes a diametral slit to be made in the abdominal wall upon puncture. It is believed that such a slit, would tend to improve healing and simulates the cut of a scalpel, rather than the standard triangular point openings as made with standard trocars. It has the added effect of quicker safety shield response time, to cover the obturator tip.

Furthermore, it has been found that trocar obturators with small diameter (5 mm or less), which are merely two sided

blades, need an increased mass to better puncture the abdominal wall. It is an object of the invention to provide such mass to the trocar obturator.

These and other objects of the invention are provided in a trocar which comprises an obturator connected to an obturator handle and the obturator having a sharpened tip. This obturator may be inserted into a cannula which is connected to a cannula handle. The cannula itself has an opening with an internal diameter. Also, the device contains a safety shield which is spring-loaded within the obturator handle. The safety shield is capable of covering the obturator tip. The safety shield contains within it an opening through which the obturator tip may pass. Generally, the obturator tip when it extends through the opening abuts the inner diameter of the cannula. Generally, the obturator tip is formed from an amorphous metal and contains a curved profile, forming a knife edge. The knife edge indeed may contain serrations. Also, the safety shield is conical in shape so that it is more readily able to spread tissue and has a slit which has a width extending across the inner diameter of the cannula. In one embodiment the blade is connected to a portion of the safety shield.

In operation, therefore the trocar of the present invention affords easier puncture, more rapid healing, and uses highly accurately shaped metals which allow for the rapid piercing of the abdominal wall. The trocar of this invention is able to be pressed through tissue, and yet will be protected by the covering by the safety shield over the obturator tip. The safety shield attached to the bilateral blade provides the ideal means to puncture tissue. Especially true for smaller size trocars (5 mm or less), the obturators are now made much more readily useful.

It is believed that this invention will be better understood by reference to the attached drawings taken in connection with the Detailed Description of the Invention.

#### DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a trocar with a conically shaped safety shield;

FIG. 2 is a bottom view of the trocar of FIG. 1;

FIG. 3 demonstrates the capability of prior art obturator tips as to piercing tissue;

FIG. 4 illustrates the obturator tip of the present invention piercing tissue;

FIG. 5 is a side view of the obturator tip of the invention taken alone without the safety shield covering it;

FIGS. 6a and 6b are alternate views of an obturator tip of this invention;

FIG. 7a is a combination view of the obturator tip of FIG. 5 covered by the safety shield, while FIG. 7b is a view of the safety shield allowing the exposure of the obturator tip of the invention;

FIG. 8 is a cross-sectional view of the trocar of FIG. 1;

FIGS. 9 and 9A are perspective views of a modified combination blade and safety shield;

FIG. 10 is a top view of FIG. 9; and

FIG. 11 is a view of FIG. 9 in the cutting position.

#### DETAILED DESCRIPTION OF THE INVENTION

A safety trocar constructed in accordance with the principles of the present invention is shown in FIGS. 1 and 8. The trocar 10 includes a trocar tube or cannula 12 having an open distal end 14 and open flanged proximal end 16. The

proximal end 16 is mounted in a trocar handle 18. There is an aperture 20 at the proximal end 16 of the trocar handle 18 which is surrounded by a gasket ring 22.

An obturator 24 is slidably and removably located within the trocar cannula 12 and is inserted into the handle 18 and trocar cannula 12 by way of the aperture 20 in the trocar cannula handle 18. Obturator 24 may reciprocate into obturator handle 28 in a slidable fashion, or conversely may rotate within handle 28. At obturator proximal end 26 is an obturator handle 28, and the distal end 30 of the obturator 24 is sharpened as a knife edge 32. The safety trocar 10 of the FIGS. 1 and 8 is used to puncture a hole in soft tissue by placing the distal end 14 of the trocar cannula 12 against tissue and pressing against the obturator handle 28. As pressure is exerted against the obturator handle 28, the safety shield 34 begins to compress the spring 36 inside the obturator handle 28, and the shield 34 retracts into the handle 28. This retraction exposes the obturator knife edge 32, which punctures the tissue.

FIG. 7b shows the shield 34 is fully compressed (within the obturator handle 28) and the obturator knife edge 32 is fully exposed beyond the distal end of the safety shield 34 and trocar cannula 12. When the obturator knife edge 32 breaks through the inner surface of the tissue, the spring-loaded safety shield 34 springs forward around the obturator distal end 30, shielding the obturator knife edge 32, to prevent inadvertent contact of the edge 32 with internal organs of the body inside the tissue being punctured.

Operation of the trocar with the safety shield of this invention is shown in FIGS. 1, 2 and 7b. FIG. 1 is a perspective view of the trocar 10 with the trocar cannula 12 held with inside trocar handle 18 so that the end of the safety shield 34 extends from the distal end 14 of the trocar cannula 12. An end view of the distal end 12 of the cannula is shown in FIG. 2. FIG. 5 is a view of the obturator 24 alone without the shield 34 over it. FIG. 7b is view of the distal end of the instrument of FIG. 1, with the knife edge 32 of the obturator 24 extended and the obturator distal end 30 moved apart from the safety shield 34. In FIG. 7a, the obturator distal end 30 is shown covered by the safety shield 34 of FIG. 7b.

While this invention has been described in general, various aspects of the device will now be described more in particular. First, it is necessary to look at the obturator distal end 30 as seen in FIGS. 1, 5, 7a and 7b, and 8. This obturator distal end 30 is generally a diametrically shaped knife edge 32. It contains two planar faces 40 which form the sharpened knife edge 32. The diametrically shaped knife edge 32 extends across the entire length L of the inner diameter of the trocar cannula. In this way, the dimensions of the knife edge 32 enable it to be placed flush against the sides S of the trocar cannula 12. This configuration lowers the force necessary to puncture and penetrate tissue. This is true because with such a knife edge 32, the obturator 24 is able to move adjacent the edges 42 of the trocar cannula 12. Therefore, when the tissue T encounters the trocar cannula 12, there is no further spreading of tissue by the cannula 12. This is in contrast with the trocar of the prior art inventions, (as seen in FIG. 3) tissue cannot be caught between the obturator tip and the safety shield.

It should be noted that knife edge 32 should be taken in conjunction with the safety shield 34 of this invention. It will be noticed that the safety shield 34 is conical in shape. This conically-shaped safety shield, generally made of a plastic, will cause the tissue to spread in a very gradual fashion. Of course, the conical shape may be steeper or shallower with respect to the diameter of cannula 12 dependent on the

desired severity of puncture. Naturally, a steeper (longer) conical height will provide smoother puncture. In addition, because the safety shield 34 also abuts the internal diameter of the trocar cannula 12, the safety shield 34 also is able to perform better spreading of the tissue.

It will be seen that the knife edge 32 at its bottom as in FIG. 2 forms a rather long diametral slits. This is different than the traditional triangular shaped cuts made by traditional trocars. This cut is more like the cut of scalpel. In this way, tissue healing will be promoted in that less tissue must be brought together at the skin surface. Also, because the tissue is very readily pierced, this formulation of the knife edge 32 and safety shield 36 enables easier force to pierce during piercing.

As seen in FIGS. 6a and 6b, there are shaped two alternate forms of knife edges, 32A, 32B, both based on a diametral slit design. In one knife edge 32A contains a serrated edge. This serrated edge 32A is able to cut through tissue with a much greater ease. Of course, the serrated edge 32A creates greater surface area contact in tissue, but does not detract from the size or shape of the knife edge.

Alternately, in FIG. 6b, there is described a tip 32B with a generally scalpel shape. This scalpel shape used in conjunction with a safety shield compatible with it allows the user to pierce the tissue using the same holding position as using a scalpel. This can be particularly useful for endoscopic applications of such a knife edge 32B. These knife edges may be placed at an angular orientation to form a cutting shape between 10° and 60° with the sides of the cannula 12.

In fact, the obturator 24 of this invention is also useful as a piercing instrument. That is, because the obturator 24 of the present design is useful to pierce tissue, much like a scalpel, this obturator 24 may be borrowed to be used endoscopically down a long trocar cannula in order to cut tissue internally. Of course, the safety shield 34 of this mechanism must be adapted so that it is able to be covered only when desired and not automatically after piercing through tissue.

The obturator 32 of this invention maybe formed from an amorphous metal, much like that described in Ser. No. 786,752, now U.S. Pat. No. 5,314,417 assigned to a common assignee as this invention. This amorphous metal can be very highly shaped and refined to very small dimensions, such as about 0.001" or less. In this way, the knife edge of this mechanism is very readily adapted to pierced tissue. Also, because the amorphous metals may be formed as serrated edges as in FIG. 6a, we are able to use such a knife edge to perform useful endoscopic functions. Nonetheless, other materials are also available, such as ceramics and the typical stainless steel, from which to form the knife edge.

A modified combination safety shield and blade is described in FIGS. 9, 10 and 11. As seen in the figures, attached to the distal end of the obturator shaft 202 which is inserted into the trocar cannula (identified as item 12 in FIG. 1) is a stationary safety shield 106 and a spring-loaded shield portion 102. At the distal end of the shield 106 is a sharpened stainless steel semicircular cutting blade 104 similar to the cutting blades shown in FIGS. 1 to 8. The stationary safety shield and blade combination (as seen in FIG. 10) encompasses half of the trocar cannula 12 cross-section such that the blade 104 extends diametrically along the circumference of the trocar cannula 12. Opposite to the stationary portion of the safety shield 106 is the spring loaded shield portion 102. The proximal end of the spring-loaded shield portion 102 is connected to the distal end of shaft 202 by a spring 200. The distal end 108 of this movable portion 102 extends to the tip of the blade 104 on the stationary portion 106. Thus, when this movable portion 106 is in its distalmost

position, and locked thereto, by known conventional locking means (also not shown), the blade 104 is protected from cutting tissue. On the other hand, when the movable shield portion is unlocked, the shield 102 is able to retract proximally into the cannula. In this fashion, the blade 104 becomes exposed and blade tip 105 is free to cut tissue. When pressure against the movable safety shield portion 102 is removed, the movable shield 102 returns to its fully extended position and locks in that position. At that point, the blade no longer may cut tissue.

This embodiment is particularly suited for small (5 mm or less) trocars, as the blade 104, which is quite thin (less than 0.005"), is reinforced by the stationary shield 106. This mass added to blade 104 provides a useful platform on which to cut tissue.

This new trocar presents many improved uses. There are also equivalents that can be discerned from the description of this invention. Such equivalents are intended to be covered by the scope of this invention as to be derived from the attached claims.

What is claimed is:

1. A trocar obturator comprising:  
an elongated shaft having a distal end and a proximal end;  
a blade with a distal cutting end and a proximal end, said blade proximal end attached to the distal end of said shaft;  
a stationary shield portion affixed to said blade, said stationary shield portion having a distal end and a proximal end;  
a movable shield portion attached by a spring to the distal end of said shaft, said movable shield portion slidable with respect to said stationary shield portion and said blade, such that said movable shield portion may be retracted proximally from the distal cutting end of said blade to allow cutting by said blade;  
wherein said blade distal cutting end extends distally from said stationary shield distal end, and said blade distal cutting end is generally semicircular in shape.
2. The obturator of claim 1 wherein said trocar obturator is part of a trocar system comprising at least a cannula into which said obturator is insertable.
3. The obturator of claim 2 wherein said cannula is 5 mm or less in diameter.
4. A trocar obturator comprising:  
an elongated shaft having a distal end and a proximal end;  
a blade with a distal cutting end and a proximal end, said blade proximal end attached to the distal end of said shaft;  
a stationary shield portion affixed to said blade, said stationary shield portion having a distal end and a proximal end;  
a movable shield portion attached by a spring to the distal end of said shaft, said movable shield portion slidable with respect to said stationary shield portion and said blade, such that said movable shield portion may be retracted proximally from the distal cutting end of said blade to allow cutting by said blade;  
wherein said blade distal cutting end extends distally from said stationary shield distal end, and said blade distal cutting end is generally semicircular in shape; and  
further comprising locking means to lock said movable shield portion in a locked position with respect to said stationary shield portion and said blade so that the respective distal ends of said movable shield portion and said blade are coextensive in said locked position.

\* \* \* \* \*



US005545150A

**United States Patent**

[19]

**Danks et al.****Patent Number:** 5,545,150**Date of Patent:** Aug. 13, 1996**[54] TROCAR****[75] Inventors:** John K. Danks, Boca Raton, Fla.; Richard V. Mazzola, Bloomfield, N.J.; Thomas R. Johnson, Milford, N.H.**[73] Assignee:** Endoscopic Concepts, Inc., Delray Beach, Fla.**[21] Appl. No.:** 238,959**[22] Filed:** May 6, 1994**[51] Int. Cl.:** A61M 5/00; A61M 5/14**[52] U.S. Cl.** 604/256; 604/265; 604/169; 604/167**[58] Field of Search** 604/265, 264, 604/256, 263, 272, 51, 169, 167, 172, 280, 164, 158, 244-246; 137/527.6; 251/149.1, 149.2**[56] References Cited****U.S. PATENT DOCUMENTS**

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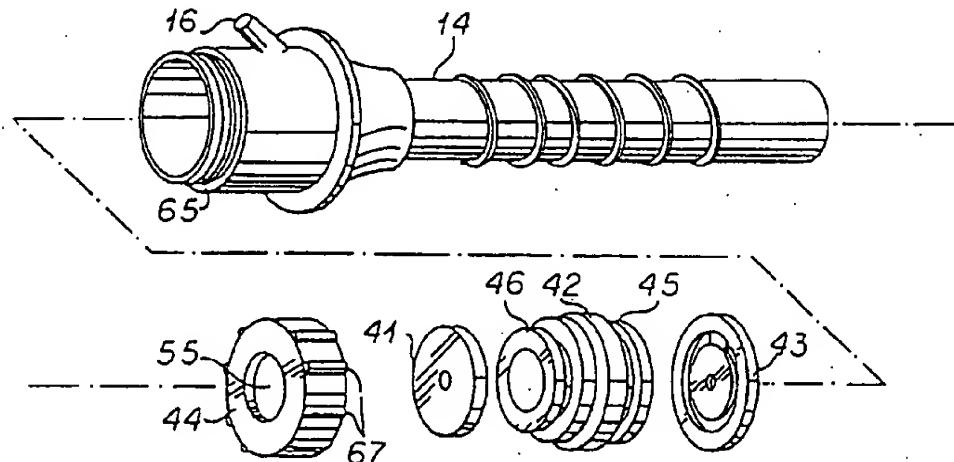
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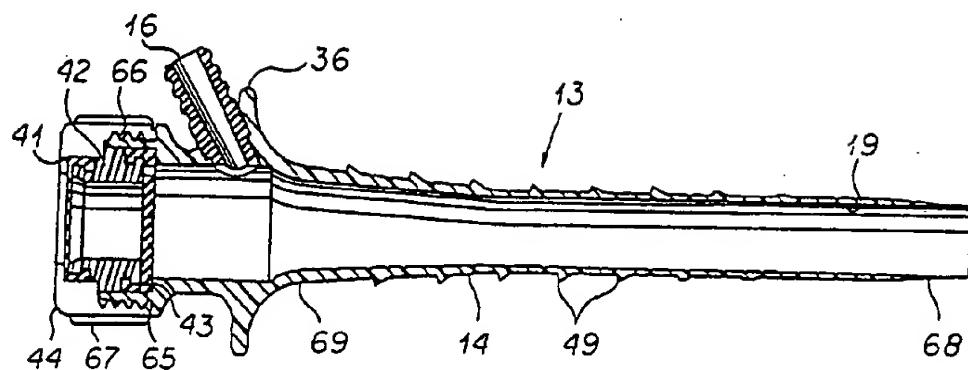
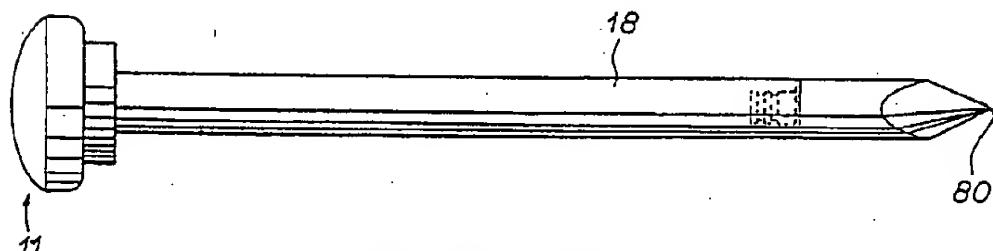
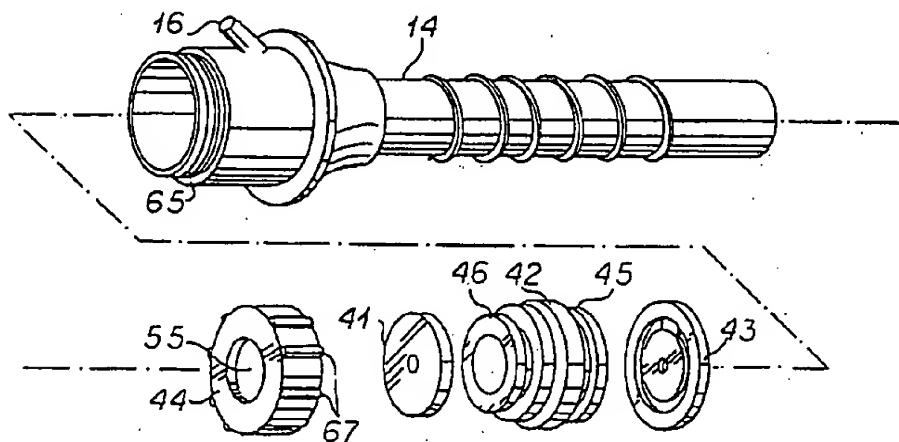
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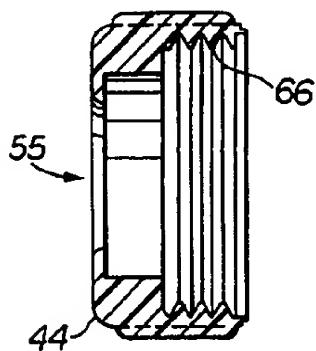
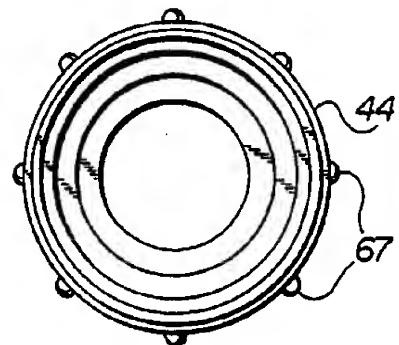
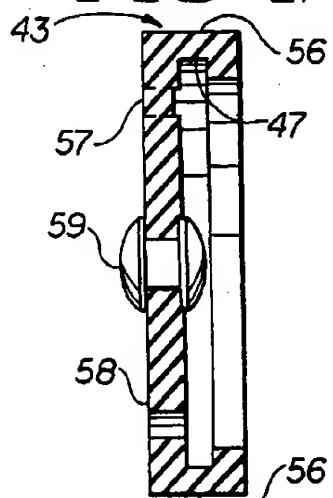
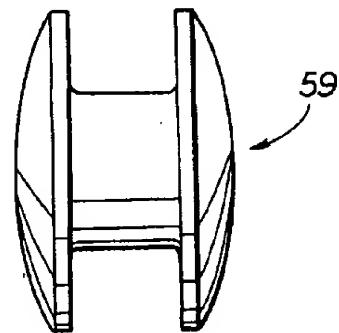
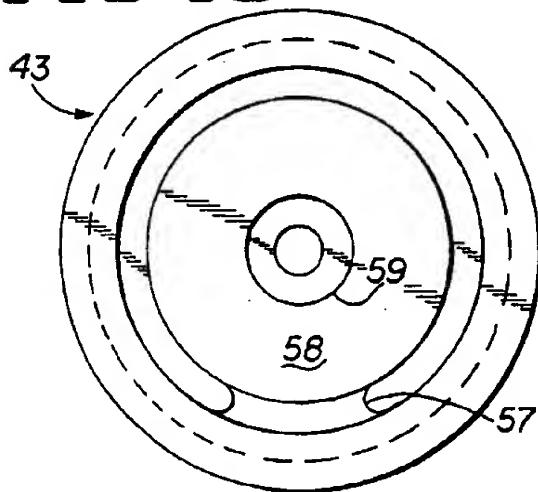
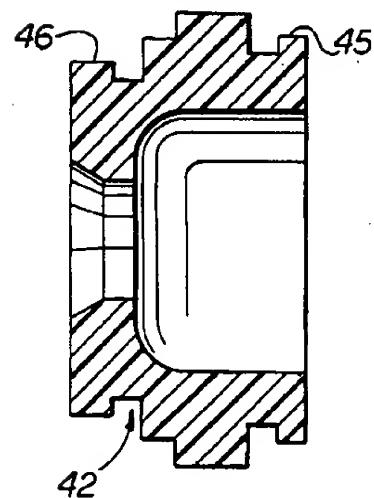
**Primary Examiner**—John D. Yasko**Assistant Examiner**—Ronald K. Stright, Jr.**Attorney, Agent, or Firm**—Miller & Martin**[57] ABSTRACT**

A trocar is formed from a cannula and an interfitting obturator for penetrating body cavity walls in laparoscopic and endoscopic surgery. The obturator is provided with an improved piercing tip having a pointed blade and an improved double locking blunt nosed shield design. Hydrophilic coatings or components are also employed on the shield and cannula to facilitate quicker shield action covering the pointed blade and ease of entry of the cannula tube through the body cavity wall. The cannula also has an improved inexpensive flexible flapper valve and can be manufactured with a reusable cannula tube but disposable flapper valve assembly to minimize cost.

14 Claims, 5 Drawing Sheets



**FIG 1A****FIG 1B****FIG 2**

**FIG 3A****FIG 3B****FIG 4A****FIG 4B****FIG 4C****FIG 5**

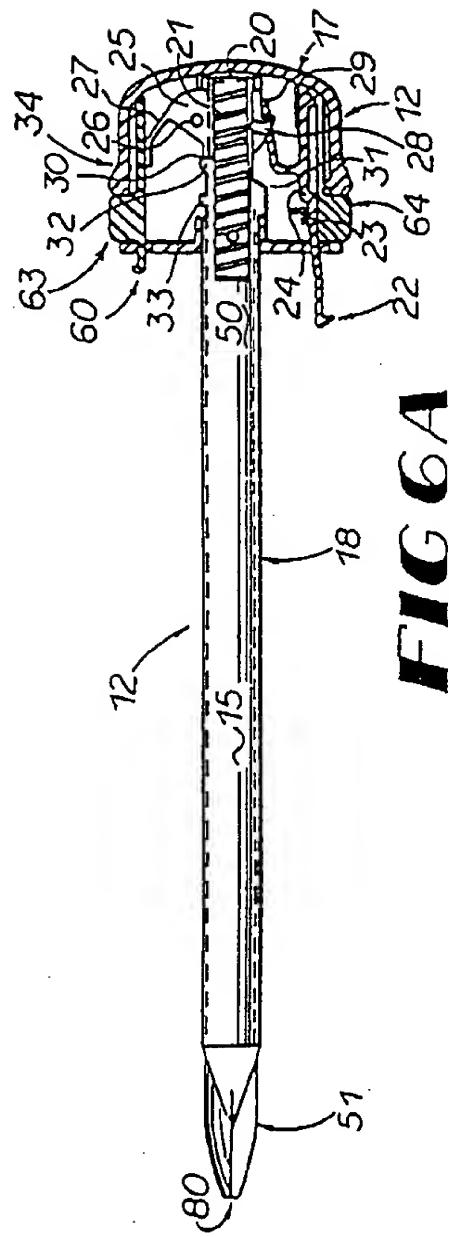


FIG 6A

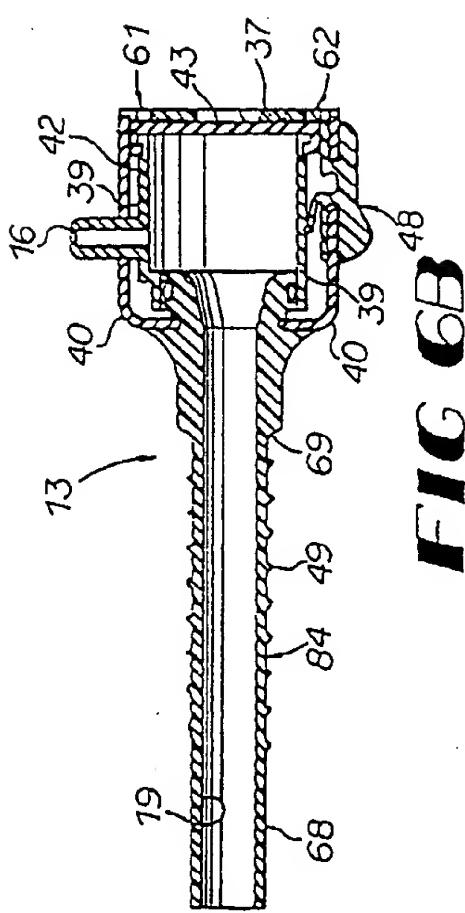
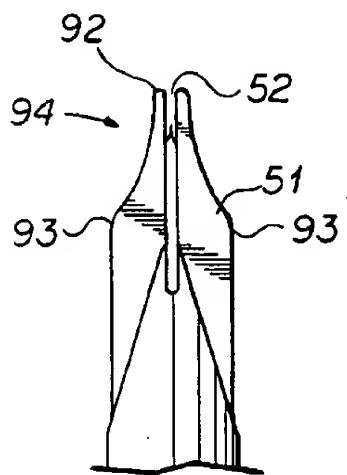
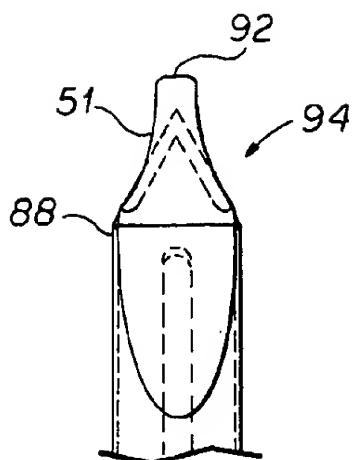
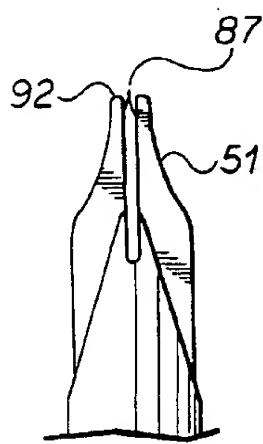
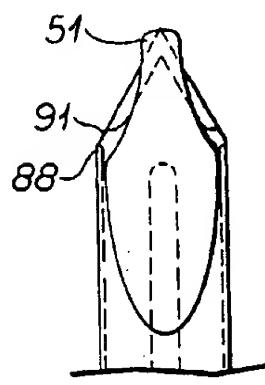
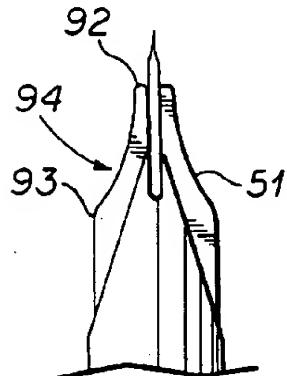
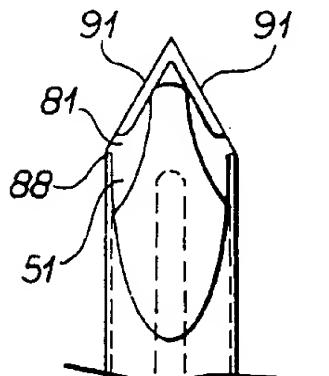
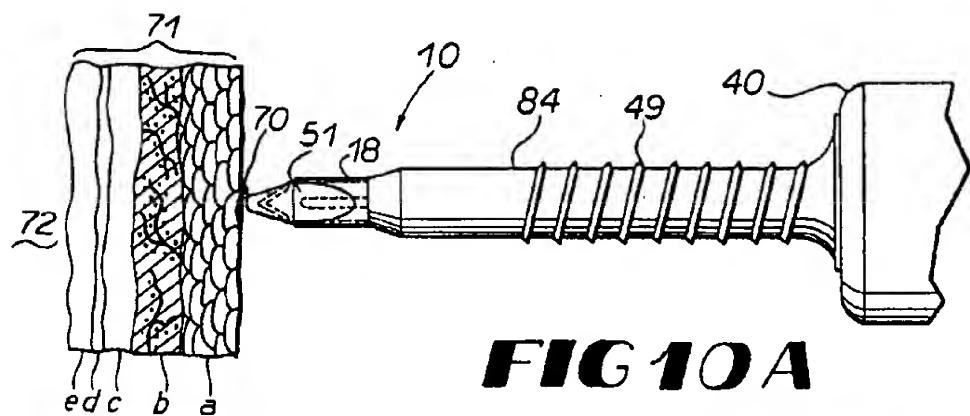
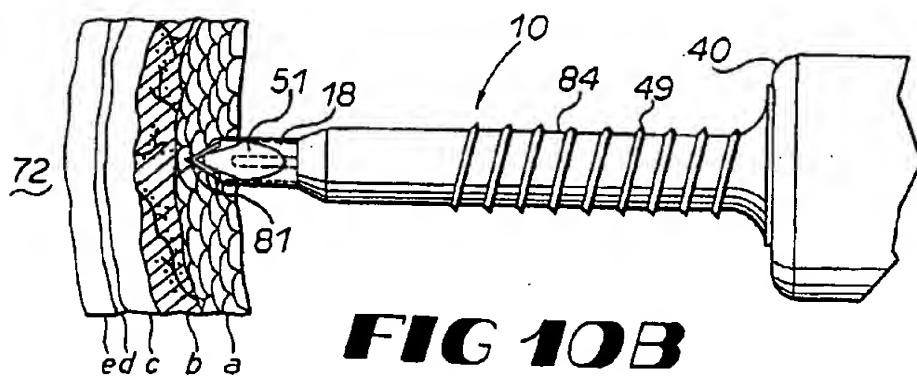
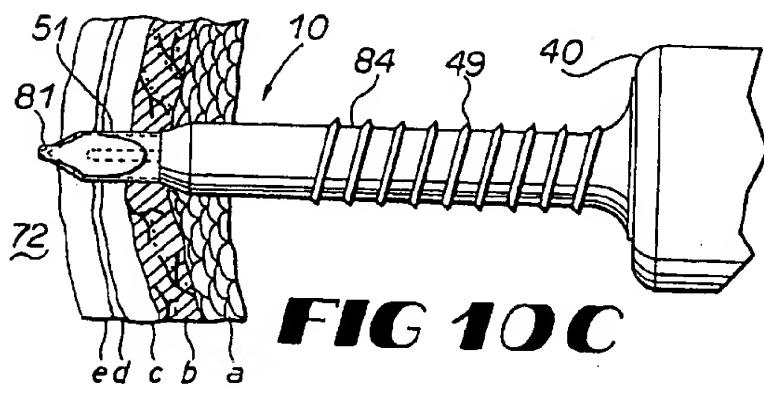
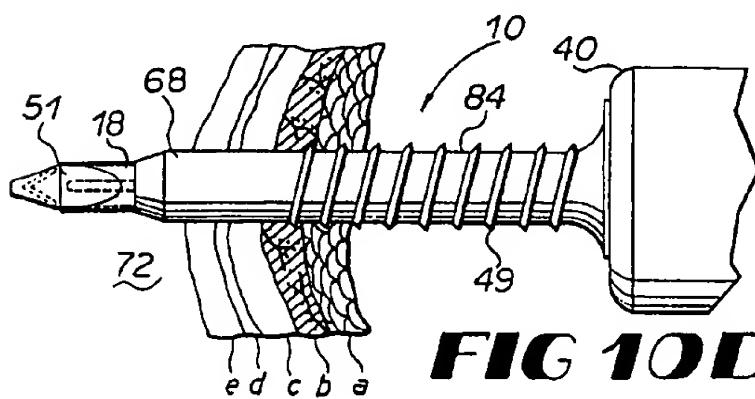


FIG 6B

**FIG 7A****FIG 7B****FIG 8A****FIG 8B****FIG 9A****FIG 9B**

**FIG 10A****FIG 10B****FIG 10C****FIG 10D**

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**TROCAR**

**BACKGROUND OF THE INVENTION**

The present invention relates to a surgical instrument commonly referred to as a trocar, or an obturator and cannula, often used in laparoscopic or arthroscopic surgery. More particularly, the invention relates to new and improved designs for shields, seals, and coatings, and to the use of disposable seal and stopcock assemblies on an otherwise reusable instrument.

Many surgical procedures are now being performed with the use of trocars and cannulas. Originally these devices were used for making a puncture and leaving a tube to drain fluids. As technology and surgical techniques have advanced, it is now possible to insert surgical instruments through the cannulas and perform invasive procedures through openings less than half an inch in diameter. Previously these procedures required incisions of many inches. By minimizing the incision, the stress and loss of blood suffered by patients is reduced and the patients' recovery times are dramatically reduced.

Surgical trocars are most commonly used in laparoscopic surgery. Prior to use of the trocar, the surgeon will usually introduce a Veress needle into the patient's abdominal cavity. The Veress needle has a stylet which permits the introduction of gas into the abdominal cavity. After the Veress needle is properly inserted, it is connected to a gas source and the abdominal cavity is insufflated to an approximate abdominal pressure of 15 mm Hg. By insufflating the abdominal cavity, pneumoperitoneum is created separating the wall of the body cavity from the internal organs.

A trocar is then used to puncture the body cavity. The piercing tip or obturator of the trocar is inserted through the cannula or sheath and the cannula partially enters the body cavity through the incision made by the trocar. The obturator can then be removed from the cannula and an elongated endoscope or camera may be inserted through the cannula to view the body cavity, or surgical instruments may be inserted to perform ligations or other procedures.

A great deal of force is often required to cause the obturator to pierce the wall of the body cavity. When the piercing tip breaks through the cavity wall, resistance to penetration ceases and the tip may reach internal organs or blood vessels, with resultant lacerations and potentially serious injury. The creation of the pneumoperitoneum provides some free space within which the surgeon may stop the penetration of the trocar. To provide further protection, trocars have more recently been developed with spring loaded shields surrounding the piercing tip of the obturator. Once the piercing tip of the obturator has completely pierced the body cavity wall, the resistance of the tissue to the spring loaded shield is reduced and the shield springs forward into the body cavity and covers the piercing tip. The shield thereby protects internal body organs and blood vessels from incidental contact with the piercing tip and resultant injury. Trocars including various safety shield designs are described in Yoon, U.S. Pat. Nos. 4,535,773; Moll, 4,654,030; and Moll, 4,601,710. An improved piercing tip comprised of a pointed blade with an improved safety shield is also the subject of commonly owned pending U.S. Ser. No. 08/038, 904.

Once the cannula has been introduced into the opening in the body cavity wall, the pneumoperitoneum may be maintained by introducing gas into the abdominal cavity through the cannula. Various seals and valves have been utilized to

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 allow abdominal pressure to be maintained in this fashion. Maintaining abdominal pressure is important both to allow working room in the body cavity for instruments introduced through the cannula, and to provide free space for the puncturing of the body cavity wall by one or more additional trocars as may be required for some procedures.

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 While the existing trocars and cannulas have proven useful, several disadvantages remain. The force required to cause the piercing tip to penetrate a body cavity wall is often so great that some physicians must strain to use the trocar with resulting loss of control over the depth of penetration of the instrument. In addition, the existing shield mechanisms do not spring forward to cover the obturator tip as quickly as possible. The delay in covering the piercing tip exposes the patient to unnecessary risk of internal laceration.

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 Also, with the current emphasis on cost controls in health care, it is desirable to utilize reusable medical instruments whenever possible. The difficulties of cleansing, disinfecting and otherwise decontaminating used trocars has made this a time consuming or impossible task, especially for shielded trocars. Therefore, a need exists for an improved apparatus for performing laparoscopic and similar surgical procedures.

**SUMMARY OF THE INVENTION**

Accordingly, it is the primary object of the invention to provide a safer trocar for piercing body cavity walls.

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 It is also an object of the invention to provide an improved shield design which will provide faster coverage of the obturator's piercing tip.

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 It is a further object of the invention to provide improved coatings for shields and cannulas which will permit easier penetration of body cavity walls and faster coverage of the obturator's piercing tip.

It is another object of the invention to provide a cannula which may be substantially reused without the need for excessive labor in cleaning and decontamination.

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 It is still another object of the invention to provide a seal or valve which permits easy insertion of surgical and exploratory instruments through the cannula yet still operates effectively to maintain the pneumoperitoneum in the body cavity.

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 Accordingly, the present invention provides a cannula with a detachable cap and disposable seal assembly and stopcock. To achieve faster shield protection, the forward or distal end of the shield is bottle shaped and is biased to move forward to cover the obturator's piercing tip when the piercing tip penetrates the body cavity wall. The shield may also be fabricated from or treated with hydrophilic materials so that when it is dipped in sterile water or other wetting solution before use, there is less friction between the shield and the body cavity wall allowing faster coverage of the piercing tip. To achieve easier penetration of body cavity walls by the cannula, the cannula may also be treated with a hydrophilic coating. A novel and inexpensive flexible valve is also provided which facilitates insertion of surgical instruments.

**BRIEF DESCRIPTIONS OF THE DRAWINGS**

FIG. 1A is a cross sectional side view of an improved cannula according to the invention with a disposable gland retainer and end cap.

FIG. 1B is a side view of a conventional obturator which is adapted for use with the cannula of FIG. 1A.

FIG. 2 is an exploded perspective view of the improved cannula of FIG. 1.

FIG. 3A is a cross sectional side view of the end cap of the improved cannula of FIG. 1 in isolation.

FIG. 3B is an end view of the end cap of the improved cannula of FIG. 1.

FIG. 4A is a cross sectional side view of the flexible flapper valve of the improved cannula of FIG. 1 in isolation.

FIG. 4B is an enlarged side plan view of the button which is mounted in the center of the preferred embodiment of the flexible flapper valve.

FIG. 4C is an end view of the flexible flapper valve of the improved cannula of FIG. 1.

FIG. 5 is a cross sectional side view of the gland retainer of the improved cannula of FIG. 1 shown in isolation.

FIG. 6A is a side view in partial cross section of an obturator with an improved shield design and mechanism according to the present invention.

FIG. 6B is a cross sectional side view of a cannula with a flexible flapper valve for use with the obturator of FIG. 6A.

FIG. 7A illustrates a side view of the improved shield design in its fully extended position covering the pointed blade of the obturator.

FIG. 7B illustrates a top view of the shield of FIG. 7A.

FIG. 8A illustrates a side view of the improved shield design in a partially retracted position exposing only portions of the sharpened edges of the pointed blade of the obturator, but covering the sharp tip of the blade.

FIG. 8B illustrates a top view of the shield of FIG. 8A.

FIG. 9A illustrates a side view of the improved shield design in a fully retracted position exposing the tip and sharpened edges of the pointed blade of the obturator.

FIG. 9B illustrates a top view of the shield of FIG. 9A.

FIGS. 10A through 10D show, in sequential diagrammatic sectional views, an embodiment of the present invention as used to puncture a body cavity wall of a patient.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

The invention commonly known as a trocar is comprised of two major components. These are a cannula 13 such as those illustrated in FIGS. 1A and 6B, and an obturator such as the traditional obturator 11 in FIG. 1B or the shielded obturator 12 illustrated in FIG. 6A. The obturator 11 of FIG. 1B and cannula 13 of FIG. 1A are interfiting and as explained below are used together to penetrate a body cavity wall. Once the body cavity wall is penetrated, however, the obturator 11 may be removed and other medical instruments may be introduced into a lumen 19 of the cannula 13.

The cannula 13 of FIG. 1A consists of three components and two seal assemblies. The components are the cannula tube 14, the gland retainer 42 and the cap 44. The outer surface of the cannula tube 14 of FIG. 1A is shown with a helically wound thread 49 preferably beginning at a reduced height a short distance from the distal end 68 of the cannula tube 14 and gradually increasing to its full height as it proceeds toward the proximate end 69. At the proximate end 69 of the cannula tube 14, there is a raised flange 36 for convenience in handling the cannula 13. The proximal end of the cannula above the raised flange 36 forms a handle. Above the flange 36 is a gas port 16 which can be connected to a gas supply, not shown, to supply gas through the lumen 19 of the cannula tube 14 into a body cavity to create or

maintain pneumoperitoneum. Above the gas port 16 are male threads 65 which allow the cannula tube 14 to be securely coupled with cap 44 which has corresponding female threads 66. The cap 44 also has an aperture 55 to permit insertion of an obturator 11, and gripping protrusions 67 to facilitate fastening and unfastening the cap 44. Mounted concentrically mostly within the proximate end 69 of the cannula tube 14 and held in place by the cap 44 is the gland retainer 42. The cap 44 is shown in isolation in FIGS. 3A and 3B.

The gland retainer 42 shown in isolation in FIG. 5, holds two seals, 43 and 41, in place. Flexible flapper seal 43 shown in FIG. 4A has an annular outer casing 56 which engages the gland retainer 42. A raised edge 45 at the distal end of the gland retainer 42 fits within a channel 47 shown in FIG. 4A formed by the lips of the C shaped edge formed by a lip of the outer casing 56 of flexible flapper seal 43, shown in FIGS. 1A and 2. A second raised edge 46 at the proximate end of the gland retainer 42 fits with a channel formed by a similar C shaped edge of the outer casing of wiper seal 41. Both the membrane seal 41 and flexible flapper seal 43 are fabricated from materials having sufficient elasticity that the outer casings of the seals 41 and 43 can be stretched over ridges 46 and 45 respectively.

The wiper seal 41 is of conventional design, however, the flexible flapper valve 43 is of novel construction. As shown in FIGS. 4A and 4C, a hinge 57 extends inward from the outer casing 56 of the flexible flapper valve 43 and mounted on the hinge is the flapper 58. In the preferred embodiment a hard plastic or metal button 59 is mounted on or through the flapper. When the piercing tip 80, shown in FIG. 1A, of an obturator 11 is inserted through the opening 55 in the cap 44, and through the wiper seal 41, the piercing tip contacts the hard button 59 of the flexible flapper valve 43 and begins to deflect the flapper 58 from its normal closed position flush against the distal end of the gland retainer 42. Because the flapper 58 is preferably molded or stamped in one piece with the hinge 57 and outer casing 56 of an elastomeric material, the piercing tip of the obturator might otherwise penetrate or cut into the flapper 58 which could cause resistance to entry of the obturator or damage the flapper 58 so that it would no longer seal the cannula 13 or gland retainer 42 effectively against loss of air through the opening 55 in the cap 44. The hard button 59 alleviates these possible problems.

When the obturator 12 or other endoscopic instrument is removed from the cannula 13, the resiliency of the hinge 57 causes the flapper 58 to move to a partially closed position. The flapper 58 is then firmly closed and sealed by action of the air pressure from the inflated body cavity, such air pressure pushing the flapper 58 against the edges of the distal end of the gland retainer 42 and thereby forming an effective seal against further loss of gas.

In its preferred embodiment, the cannula tube 14 portion is manufactured of a durable material such as stainless steel or titanium alloys, capable of withstanding repeated high temperature cleaning and sterilization, while the gland retainer 42 is made of an inexpensive plastic. The cap 44 may be made of either type of material. The gland retainer 42, containing the flapper valve and possibly also containing a wiper seal, is difficult to clean and sterilize. However, the gland retainer 42 and seals 41 and 43 are relatively inexpensive to manufacture and can be discarded after each use. The cannula tube 14, and optionally the cap 44, are relatively easy to clean and sterilize and need not be discarded. By reusing the cannula tube 14, and the cap 44 if manufactured of an appropriate material, cost and waste can be minimized. If desired the cap 44 can also be manufactured of inexpen-

sive plastic and discarded with the gland retainer 42 after use.

A shielded obturator 12 is shown in greater detail in FIG. 6A. The shielded obturator 12 in FIG. 6A includes an obturator housing 17 which forms a grip or handle. The shielded obturator 12 also includes a hollow obturator sheath 18, the proximal end of which is mounted to the obturator housing 17. The distal end of the obturator sheath 18 is fitted with a piercing tip 80. Housed within the obturator sheath 18 is the shield 15, shown in its extended position with the distal end 51 covering the piercing tip 80. The proximal end 50 of the shield 15 is received some distance within the hollow obturator sheath 18 where it is outwardly biased by a biasing means such as the coiled spring 21 interposed between the proximal end 50 of the shield 15 and the inner wall 20 of the obturator housing 17.

Still referring to FIG. 6A, a double action latch 34 for locking the shield 15 in both the extended position and a partially retracted position is illustrated. The latch 34 comprises a biasing means such as the spring 27, a blocking member such as the illustrated pivoting chock 25, an actuator such as the trigger 48, shown in FIG. 6B, and a linkage between the actuator and the blocking member such as the linking member 24. The illustrated latch operates to keep the shield 15 locked in the extended position except when armed or actuated. To lock the shield 15, a solid portion 30 of the pivoting chock 25 engages with a first lug 32 on the proximal end 50 of the shield 15 to prevent the shield 15 from retracting further toward the inner wall 20 of the obturator housing 17 and thereby exposing the piercing tip 80.

In order to permit the shield 15 to be retracted, the latch 34 must first be armed or actuated. To accomplish this, the shielded obturator 12 and cannula 13 must first be interfitted. In FIGS. 6A and 6B, the distal end 22 of the linking member 24 from the shielded obturator 12 is received through opening 62 and engaged in the trigger 48 mounted in the cannula 13. Also a guiding tab 60 from the shielded obturator 12 is received in an opening 61 in the cannula 13. By depressing push buttons 63 and 64, the guiding tab 60 and linking member 24 can be disengaged, allowing for easy separation of the shielded obturator 12 from the cannula 13.

To arm the latch 34 in the embodiment illustrated in FIG. 6A, the distal end 22 of the linking member 24 engages with a trigger 48, shown in FIG. 6B. When the trigger 48 is depressed and pushed forward toward the piercing tip 80, the linking member 24 is likewise pulled forward. A hook 29 on the proximate end of the linking member 24 is engaged in a cradle 28 on the pivoting chock 25. As the linking member 24 is pulled forward, it causes the pivoting chock 25 to turn on its pivot 26 and thereby rotates the solid portion 30 away from the lug 32 on the proximal end 50 of the shield 15. This arms or actuates the obturator 12.

As the trigger 48 continues forward, the linking member 24 also travels forward until a stop block 23 halts further movement. When the stop block 23 halts further movement, the linking member 24 is in measured close proximity to a cam 31 protruding from the proximal end 50 of the shield 15. As soon as the surgeon applies pressure to the trocar 10, the proximal end 50 of shield 15 is pushed back into the housing 17. After the shield 15 is pushed back sufficiently that a second lug 33 on the proximal end 50 of the shield 15 has reached the solid portion 30, the cam 31 on the proximal end 50 of the shield 15 then dislodges the hook 29 of the linking member 24 from the cradle 28 of the pivoting chock 25. A biasing means such as the spring 27 acting on the pivoting

chock 25 now causes the solid portion 30 of the pivoting chock 25 to try to return to its original locking position. When the shield 15 is fully retracted, the pivoting chock 25 cannot return to a locking position. Yet if the shield 15 should extend even partially, so that it is no longer fully retracted, the solid portion 30 of the pivoting chock 25 can engage the second lug 33, and become locked against the shield again becoming fully retracted. This is referred to as a partially locked or semi-protective position. In this fashion the second lug 33 acts as a detent allowing the shield to ratchet forward to an extended position.

If the distal end 51 of the shield 15 and piercing tip 80 are properly designed, the partially locked position can provide substantial protection to the patient. With the pointed blade designs discussed in FIGS. 7-9, it is possible to have the shield cover the sharp tip 87 of the blade and allow only the sharpened edges 91 of the blade to remain exposed as shown in FIG. 8. This allows the sharpened edges 91 to continue cutting the body cavity wall but without risk of exposing the sharp tip 87 thus reducing the chance of inadvertent injury during the incision.

When the entire piercing tip 80 of the obturator 12 has passed through the body cavity wall and there is no resistance to the spring loaded shield the shield 15 will spring completely forward to cover the piercing tip 80, as shown in FIGS. 6A and 7, and the pivoting chock 25 will pivot into its original locking position, where the solid portion 30 of the pivoting chock 25 acts to block rearward movement of the first lug 32 on the proximate end 50 of the shield 15. In this fashion, once the body cavity wall has been pierced by the sharp tip 87 and the shield 15 has partially locked, the shield 15 cannot again retract to expose the sharp tip 87 of the piercing tip 80 unless the operating physician uses the trigger 48 to rearm the trocar 10. Once the piercing tip 80 has completely penetrated the body cavity wall and the shield 15 has fully locked, the shield 15 cannot again retract to oppose any portion of the piercing tip 80.

Referring again to FIG. 6B, the cannula 13 includes an outer housing 40, an inner housing 39, and a cannula tube 84 which is secured to and extends from the inner housing 39. In addition, the inner housing 39 is mounted within the outer housing 40. The inner housing 39 contains a gas sealing means such as the illustrated flexible flapper valve 43. The flexible flapper valve 43 will allow the introduction of the obturator sheath 18 of a shielded obturator 12, or other endoscopic instruments (not illustrated) without substantial loss of gas from the body cavity. As shown in FIG. 6B, when no instrument is inserted, the flapper 43 closes against the end plate 37 to maintain the gaseous pressure in the body cavity.

FIGS. 7-9 illustrate the presently preferred embodiment of the piercing tip 80, which is comprised of a pointed blade 81. The illustrated pointed blade 81 is substantially planar and has a central sharp tip or pointed distal end 87 and straight sharpened edges 91 proceeding from both sides of said distal end 87 to the shoulders 88. In alternative constructions, the blade 81 may have slight convex or concave curve to the sharpened edges 91. The point of the blade may be acute as illustrated or rounded. Other variations of a pointed blade or blades may also be utilized.

As shown in FIGS. 7A and 7B, the distal end 51 of the shield 15 used with the illustrated pointed blade is "bottle shaped" or "dolphin nose shaped" in that it has a blunt end 92 at its most distal point which widens slowly at first and then more rapidly so that there is a slight concavity 94 as the distal end 51 of the shield 15 proceeds from the blunt end 92

to a shoulder 93. As shown in FIGS. 8A and 8B, when the shield end 51 is of this shape, it is possible for the blunt end 92 to cover the pointed distal end 87 of the blade 81 so that no additional penetration is possible, while still leaving portions of the sharpened edges 91 exposed. In this fashion, when the pointed distal end 87 of the blade 81 has penetrated the body cavity wall, but before the blade 81 is entirely through the wall, the blunt end 92 of the shield can move forward and be partially locked while still allowing the sharpened edges 91 of the pointed blade 81 to expand the incision in the body cavity wall so that the obturator and cannula may be introduced to communicate with the body cavity.

FIGS. 10A through 10D illustrate the piercing tip 80 and shield end 51 of the trocar 10 formed from the obturator 12 and cannula 13 of FIGS. 6A and 6B in use. In FIG. 10A, a small incision 70 is made in the surface of the skin or epidermis "a" of the body cavity wall 71 of a patient. The piercing tip 80, in this case the pointed blade 81, of the trocar 10 with extended shield 15 may then be placed against the incision 70 as shown. When the trocar 10 is in this position, it may be armed or actuated by depressing the trigger 48 (shown in FIGS. 6A and 6B) and sliding the trigger 48 forward as explained above. When manual force is applied to the obturator housing 17 which forms the trocar handle (shown in FIG. 6A) pushing the trocar to the left, the resistance of the body cavity wall 71 holds back the distal end 51 of the shield 15 and the pointed blade 81 is exposed as shown in FIG. 10B. The pointed blade 81 then slices through the dermis "a" and subcutaneous tissue including fat cells, muscle, and fascia, depicted as "b," "c," "d" and "e" in FIGS. 10A-10D. The various layers of the body cavity wall 71 vary depending upon the cavity being pierced, but in general, the layers of fascia are particularly resistant to penetration.

In FIG. 10C, immediately after the sharpened tip 87 of the pointed blade 81 has penetrated the innermost layer "e" of the body cavity wall 71, the blunt end 92 of the distal end 51 of the shield 15 is forced forward through the incision 70 by the bias of the coil spring 21. When the shield 15 reaches this partially retracted position and the preferred double action latch 34 of the obturator 12 illustrated in FIG. 6A is used, the shield 15 will lock so that it cannot be retracted to again expose the sharp tip 87 of the pointed blade 81, yet the shield 15 permits the sharp edges 91 of the blade 81 to continue cutting. This is a semi-protected shield position. In this partially locked or semi-protected position the interior of the body cavity 72 and organs, blood vessels and other anatomical structures are protected against puncture by the sharp end 87 of the blade 81.

FIG. 10D shows that the shield end 51, the obturator sheath 18, and the distal end 68 of the cannula tube 84 all proceed through the incision 70 in the body cavity wall 71 as manual force continues to be applied to the trocar 10. Just as the shoulder 93 of the distal end 51 of the shield 15 passes through the inner layer "e" of the body cavity wall 71, the resistance of the body cavity wall 71 is significantly reduced and the shield 15 is pushed to its fully extended position with the distal end 51 covering the pointed blade 81. This action completely protects the interior of the body cavity 72 immediately after the full penetration of the pointed blade 81 through the body cavity wall 71 and protects organs, blood vessels and other anatomical structures from incidental contact even with the sharpened edges 91 of the blade 81. Simultaneously with the full extension of the shield 15 into its protective position covering the pointed blade 81, the pivoting chock 25 engages the first lug 32 on the proximate

end 50 of the shield 15, which prevents the shield 15 from being retracted to expose the pointed blade 81 until the trocar 10 is again actuated by depressing and moving the trigger 48 forward.

In order to improve the performance of the shield 15 in moving forward through the body cavity wall, it is possible to either mold the shield 15 or shield end 51 from a hydrophilic plastic or to coat the shield with a hydrophilic coating. By providing the shield end 51 with appropriate hydrophilic properties, the shield end 51 can be dipped in a wetting solution, usually of water or an appropriate alcohol solution, and the shield end 51 will then have a lower coefficient of friction and will more easily slide through the incision 70 in the body cavity wall 71 to cover the piercing tip 80. Appropriate coatings or compounds must be substantially nonreactive with respect to living tissue and non-thrombogenic when in contact with blood. Appropriate hydrophilic coatings would include polyvinylpyrrolidone-polyurethane or polyvinylbutyrol interpolymers as described in U.S. Pat. Nos. 4,100,309 and 4,119,094. Appropriate molding compounds, which could alternatively also be applied as coatings, include hydrophilic polymer blends with thermoplastic polyurethane or polyvinylbutyrol and hydrophilic polyvinylpyrrolidone or other poly(N-vinyl lactans) as described in U.S. Pat. Nos. 4,642,267 and 4,847,324. An appropriate hydrophilic coating will reduce the coefficient of friction for stainless steel by over 60% and can reduce the coefficients of friction for plastics by over 90%. This permits hydrophilic plastics to be used for the shield 15 rather than steel.

The same hydrophilic coatings or compounds may also be used in the cannula 13 which will facilitate the entry of the distal end 68 of the cannula 13 into the incision made by the obturator 12. Although the sharpened blade 81 does not provide substantial resistance, some minor improvement might also be achieved by applying a hydrophilic coating to this blade 81.

Numerous alterations of the structures herein described will suggest themselves to those skilled in the art. It will be understood that the details and arrangements of the parts that have been described and illustrated in order to explain the nature of the invention are not to be construed as any limitation of the invention. All such alterations which do not depart from the spirit of the invention are intended to be included within the scope of the appended claims.

We claim:

1. A cannula comprising:
  - (a) a cannula tube with an outer surface and an interior lumen, and having a distal end and a proximate end, said proximate end forming a cannula handle;
  - (b) a gland retainer fitted adjacent to the proximate end of said cannula tube and substantially within the cannula handle, said gland retainer having a distal end and a proximate end;
  - (c) a flapper valve mounted on said gland retainer distal end, wherein the flapper valve comprises an outer casing, a hinge, and a flapper and wherein at least the outer casing and the hinge of said flapper valve are integrally fabricated from an elastomeric material; and
  - (d) a cap releasably fastened to the cannula handle thereby confining said gland retainer.

2. The cannula of claim 1 wherein the outer casing, hinge and flapper of the flapper valve are integrally fabricated from an elastomeric material.

3. The cannula of claim 2 wherein said flapper further comprises a relatively hard surfaced centrally disposed button.

4. The cannula of claim 1 wherein the flapper valve is comprised of an outer casing having two inward facing lips defining a channel,

and wherein the gland retainer distal end has a raised edge which is received within said channel.

5. A cannula comprising:

(a) a cannula tube with an outer surface and an interior lumen, and having a distal end and a proximate end;

(b) a gland retainer fitted partially within the proximate end of said cannula tube, said gland retainer having a distal end and a proximate end;

(c) a flapper valve mounted on said gland retainer distal end, said flapper valve comprising an outer casing, a hinge and a flapper and wherein at least the outer casing and the hinge of said flapper valve are integrally fabricated from an elastomeric material; and

(d) a cap releasably fastened to the proximate end of the gland retainer.

6. The cannula of claim 5 further comprising a wiper seal 20 mounted on said gland retainer proximate end.

7. The cannula of claim 6 wherein the wiper seal is comprised of a membrane and an outer casing, said outer casing having a first raised inward facing lip supporting said membrane and a second raised inward facing lip defining a

channel, and wherein said gland retainer has a raised edge which is received within said channel.

8. The cannula of claim 5 wherein the outer casing, hinge and flapper of the flapper valve are integrally fabricated from an elastomeric material.

9. The cannula of claim 8 wherein said flapper further comprises a relatively hard surfaced centrally disposed button.

10. The cannula of claim 5 wherein the flapper valve is comprised of an outer casing having two inward facing lips defining a channel, and wherein the gland retainer has a raised edge which is received within said channel.

11. The cannula of claim 5 wherein the gland retainer interfits concentrically within the cap and the proximate end of the cannula tube.

12. The cannula of claim 5 wherein the distal end of said cannula tube is provided with a hydrophilic coating.

13. The cannula of claim 5 wherein the cannula tube is manufactured from a metal selected from the group of stainless steel and titanium alloys.

14. The cannula of claim 5 wherein the gland retainer is disposable, opposite that shown in FIG. 4A

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